

BLOODBORNE PATHOGENS EXPOSURE CONTROL PLAN

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INTRODUCTION

Hepatitis B virus (HBV), Hepatitis C virus (HCV), Human Immunodeficiency virus (HIV) and other bloodborne pathogens warrant serious attention for the approximately 5.6 million people with occupational exposure to blood and other potentially infectious materials. The Occupational Safety and Health Administration (OSHA) enacted Code of Federal Regulations (CFR) Title 29 CFR 1910.1030 *Bloodborne Pathogens Standard* (“*the Standard*”) in 1991 to protect workers with potential exposure to these materials, in recognition of these hazards.,

When the law was enacted in 1991, there were about 5,000 cases of occupationally acquired Hepatitis B, annually. The estimated number of cases in 1995 was 800, indicating the effectiveness of Standard Precautions, HBV vaccinations, and other exposure-minimizing actions required by *the Standard*. Since then, the full impact of Hepatitis C, with its high rate of chronic infection and serious sequelae, has begun to be appreciated. An estimated 3.2 million people in the United States are infected, exceeding the number of those with HIV and HBV combined⁽¹⁾.

In November of 2000, requirements for assessing the feasibility of incorporating commercially available engineering controls, such as “safe needles,” were added to *the Standard*. This action also mandated solicitation of user feedback on such devices, training on their proper use, and additional record keeping requirements. The consequence has been to reduce needle stick injuries among healthcare workers⁽²⁾. In March 2000, the Centers for Disease Control and Prevention estimated that more than 380,000 percutaneous injuries from contaminated sharps occur annually among health care workers in United States hospital settings. Approximately 600,000 needle sticks occur annually and the Centers for Disease Control, in March 2000, estimates that 62-88% are preventable⁽³⁾.

The Standard applies to all occupational exposures to blood or other potentially infectious materials. Columbia employees who work with bloodborne pathogens are subject to *the Standard’s* requirements.

SCOPE and APPLICABILITY

Where potential “occupational exposure” (see DEFINITIONS section) exists, *the Standard* requires that a *Bloodborne Pathogens Exposure Control Plan (ECP)* be written. This document outlines the protective measures that will be implemented to eliminate or minimize employee exposure to blood and other potentially infectious material (OPIM) to reduce the risk of infection, including descriptions of engineering and work practice controls, personal protective equipment, HBV vaccinations, annual training, housekeeping and disinfection procedures, medical evaluations, hazard communication, and recordkeeping (see “Using the *exposure control plan*”, below). The Columbia University *ECP* also states the Morningside Campus, Manhattanville Campus and Medical Center job classifications considered potentially at risk for occupational exposure.

Columbia University Environmental Health & Safety (EH&S) will review the *ECP* and update it on an annual basis, unless changes in the workplace occur. In that case, *the Plan* will be assessed and updated immediately to accommodate workplace changes. Copies of the *ECP* will be available on the EH&S website and therefore, available to all employees. This *ECP* is also maintained as a hard copy by EH&S to ensure access to officials from regulatory bodies with jurisdiction over compliance.

The *ECP* is one component of the *Columbia University Bloodborne Pathogen Program* (“*the Program*”). *The program* has been developed to ensure protection from the risk of exposure to bloodborne pathogens, such as the Human Immunodeficiency Virus (HIV) and the Hepatitis B Virus (HBV). Another component of *the program* is the *Columbia University Bloodborne Pathogens Policy* (“*the Policy*”) (<http://ehs.columbia.edu/BloodbornePathogensExposureControlPolicy.pdf>) which has been developed to be in agreement with the regulations set forth in the *OSHA Bloodborne Pathogens Standard* 29 CFR 1910.1030. Whereas, *the Standard* is applicable to University employees, *the Policy* is applicable to all employees, students and researchers who could be "reasonably anticipated", as the result of performing their job duties, to come in contact with blood and OPIM. Another applicable policy is the Columbia University Regulated Medical Waste Policy (<http://ehs.columbia.edu/RMWpolicy.pdf>).

Elements of the *Columbia University Bloodborne Pathogen Program* (“*the Program*”):

- Written *Blood Borne Pathogens Policy* (“*the Policy*”)
- Written *Exposure Control Plan; ECP* (“*the Plan*”)
- Employee Awareness Training
- Medical Surveillance
- Hepatitis B Vaccinations

Annual review of the *Columbia University Bloodborne Pathogen Program* (“*the Program*”)

Stakeholders meet annually to review the program and this written plan. Annual review of this plan is performed to ensure that the *Columbia University Bloodborne Pathogen Program* is meeting the terms of the Code of Federal Regulations (CFR) Title 29 CFR 1910.1030 *Bloodborne Pathogens Standard*. The following items are reviewed:

1. Identification of stakeholders
2. Review of program accomplishments in prior year
3. Review of training provided
4. Review of medical surveillance program
5. Review of incidents/accidents/exposures
6. Review of sharps injury log/engineered sharps
7. Review of feedback, including concerns and suggestions, received from employees that may or may not have risk of occupational exposure
8. Review of OSHA complaints/inspections (internal/external)

9. Review of tasks that pose a risk of exposure and Job Classifications in which employees may have occupational exposure
10. New York Presbyterian BBP-ECP for concordance, where applicable.

Using the *Exposure Control Plan*

This *Exposure Control Plan* is provided to eliminate or minimize occupational exposure to bloodborne pathogens in accordance with the *OSHA Bloodborne Pathogens Standard*, 29 CFR 1910.1030. Implementation of the *ECP* will assist clinics, laboratories, and departments in attaining compliance with *the Standard*, thereby protecting our employees. It includes:

- I. Employee exposure determination and annual review
- II. Procedures for evaluating the circumstances of an exposure incident; and,
- III. Implementation of various methods of exposure control, including:
 - Standard Precautions
 - Hepatitis B vaccination and post-exposure follow-up
 - Training, Laboratory audits, and communication of hazards to employees
 - Recordkeeping
 - Engineering and Work Control Practices, including the adoption of “safe needle” devices
 - Housekeeping
 - Personal Protective Equipment
- IV. Employee Participation

Future revisions/additions to exposure-minimizing procedures and revisions to the *ECP* will result, in part, from input by employees covered by *the Standard*. Employees may provide comments regarding the *Exposure Control Plan* to the Biosafety Office (biosafety@columbia.edu or 212-305-6780). Information/feedback will be sought during and following training sessions and during EH&S activities involving accident follow-up or *ad hoc* consultations.

This document is intended to serve as the Columbia University Medical Center (CUMC), Morningside Campus (MC), Manhattanville Campus, Nevis Campus and Lamont Doherty Earth Observatory (LDEO) *Exposure Control Plan (ECP)* in compliance with OSHA regulations. The directive information herein addresses most common biological safety procedures, but Principal Investigators must be aware of their responsibility to provide additional laboratory- and task-specific details and hand-on training to the people working in their laboratories. If your laboratory is already using a safety plan with the same information as this plan, you may continue to use the existing document provided that your plan covers the same elements as this Plan.

DEFINITIONS

Blood - human blood, human blood components, and products made from human blood, including medications derived from blood, such as immune globulins, albumin, and factors 8 and 9.

Bloodborne Pathogens (BBP) - pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, Hepatitis B virus (HBV), human immunodeficiency virus (HIV), and Hepatitis C virus (HCV). Other examples include Hepatitis C, malaria, syphilis, babesiosis, brucellosis, leptospirosis, arboviral infections, relapsing fever, Creutzfeld-Jakob Disease, Human T-Lymphotropic Virus type 1, Dengue virus, Zika virus and viral hemorrhagic fever.

Cell lines – primary cultures or immortalized cells originating from humans or non-human primates. Despite [OSHA's standard interpretations](#) which states that “cell lines that are procured from commercial vendors or other sources with documented testing to be free of bloodborne pathogens and which have been protected by the employer from environmental contamination may be excluded from the bloodborne pathogens standard”, the policy at Columbia is to include human or non-human primate cell lines (regardless of being declared "pathogen-free") as having the potential to contain bloodborne pathogens. The rationale is that there are many pathogens that can reside in human cell lines, some even novel, and they are not all tested for. So for example, even though the cell line may be tested for HIV it may not be tested for Zika virus. While the testing done by commercial entities like the ATCC is trustworthy, cell lines can be purchased from other entities that may not employ the same rigor. Furthermore as cells are passaged in the lab many times and co-mingle with other infectious material in incubators they can acquire infectious agents such as retroviruses. It is more pragmatic to include all cell lines since having the investigators do their own risk assessment on the fidelity of the materials can lead to different opinions, and different evaluations of overall risk.

Contaminated - the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

Contaminated laundry - laundry, which has been soiled with blood or other potentially infectious materials or which may contain sharps.

Contaminated sharps - any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass or capillary tubes, and dental wires.

Decontamination - the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infection and the surface or item is rendered safe for handling, use, or disposal.

Engineering controls – control mechanisms, including, but not limited to, sharps disposal containers, self-sheathing needles, and safer medical devices such as sharps with engineered

sharps injury protections and needleless systems, that isolate or remove the bloodborne pathogens hazard from the workplace.

Exposure incident - a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties. "Non-intact skin" includes skin with dermatitis, hangnails, cuts, abrasions, chafing, acne, etc.

Hand washing facilities - a facility providing an adequate supply of running potable water, soap and single use towels or hot air drying machines.

Needleless systems - a device that does not use needles for (A) the collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established, (B) the administration of medication or fluids, or (C) any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

Occupational exposure – actual or reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that results or may result from the performance of an employee's duties.

Other Potentially Infectious Materials (OPIM) - (1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

Parenteral injury - piercing of mucous membranes or the skin through such events as needle sticks, human bites, cuts, and abrasions.

Personal Protective Equipment (PPE) - specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment.

Production facility - facility engaged in industrial-scale, large-volume or high concentration production of HIV or HBV.

Regulated medical waste (RMW) - liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these

materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.

Research laboratory - a laboratory handling clinical materials that may contain BBP. Research laboratories may produce or use research-laboratory-scale amounts of HIV or HBV. Research laboratories may produce high concentrations of HIV or HBV but not in the volume found in production facilities.

Safe sharps and Engineered Sharps Injury Protections (ESIP) - a non-needle sharp or needle device used for withdrawing body fluids, accessing a vein or artery, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident. To qualify as "engineered sharps injury protection" the anti-stick safety feature of the sharp must: (1) be "built into" the device; and (2) "effectively" reduces the risk of an exposure incident.

Source individual - any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to an employee. Examples include, but are not limited to, hospital and clinic patients; clients in institutions for the developmentally disabled; trauma victims; clients of drug and alcohol treatment facilities; residents of hospices and nursing homes; human remains; and individuals who donate or sell blood or blood components.

Sterilization - the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.

Standard precautions - (formerly referred to as Universal Precautions) refers to a concept of bloodborne disease control which requires that all human blood and certain human body fluids be 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 (e.g., prohibiting recapping of needles by a two-handed technique).

PROGRAM ADMINISTRATION

Environmental Health and Safety (EH&S)

- Provides Bloodborne Pathogens Awareness training, documents attendance
- Responsible for biological safety program information, and *ad hoc* biological safety issues.
- Develops and implements the *Columbia University Blood Borne Pathogens Program*.
- Develops written *Blood Borne Pathogens Policy* and amend as necessary.
- Responsible for updates of the *ECP* and providing laboratories with the most recent copy through electronic distribution.
- Performs risk assessments. Identifies, in conjunction with employee supervisors, those employees, students, and researchers, who as the result of performing their job

duties could be “reasonably anticipated” to come in contact with blood and other potentially infectious materials (OPIM); participate in annual review of job classifications and *the Plan*.

- Recommends personal protective equipment (PPE) if necessary.
- Assists in locating suppliers of “safe needles” and other products that may reduce exposure.
- Conducts investigations of exposure incidents and recommend work practice changes, if necessary.
- Conducts inspections to ensure implementation of the *ECP* and compliance with *the Standard*.

Department Heads/Employee Supervisors/Principal Investigators (PIs)

- Identify those employees who, as the result of performing their job duties, may be "reasonably anticipated" to come in contact with blood and other potentially infectious materials; participate in annual review of job classifications and *the Plan*.
- Ensure employees have received Bloodborne Pathogens training.
- Ensure that hands-on task- and laboratory-specific training is provided to laboratory personnel in addition to the training provided by EH&S.
- Ensure an adequate supply of PPE is available.

Principal Investigators have overall responsibility for health and safety compliance in their laboratory; this responsibility may be delegated to Laboratory Safety Managers or other laboratory personnel. Their review and modification of exposure control plans must reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens, and must document consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure. Updates must take into account new activities with additional exposure scenarios and document consideration of commercially available engineering controls that minimize exposure risk (e.g., in a clinical setting, adopting “safe needle” devices to start IV lines or to draw blood).

Medical Providers

Facilities that provide the medical evaluations, treatment for exposures incidents, maintain medical records and provide HBV vaccine

(<http://www.ehs.columbia.edu/WhereToGoForMedicalAttention1.pdf>):

1. **Workforce Health and Safety** (Medical Center; Harkness South, 1st Floor, 5-7590)
2. **Student Health Services** (Medical Center; 60 Haven Ave, 3rd floor, Suite 3D)
3. **Health Services at Columbia** (Morningside; John Jay Building)
4. **NYPH Emergency Room** (Medical Center; Vanderbilt Clinic, 168th Street)
5. **St. Luke’s-Roosevelt Hospital Emergency Room** (Morningside; 1111 Amsterdam Ave at 114th St.)

Regulated Medical Waste Handling

Regulated Medical Waste (RMW) collection, as required by *the Standard* and State laws, is administered differently on each campus:

- **Morningside Campus:** Sharps containers and red bag waste (deposited in grey plastic containers) is removed by third party vendor, **Approved**. Requests for service are administered through EH&S (212-854-8749).
- **Medical Center:** Sharps containers are removed by third party vendor **Stericycle**. Red bag waste (deposited in grey plastic TB02 or authorized cardboard containers) is removed by **Facilities Operations**. Requests for service are administered through CUMC Facilities Operations (212-305-7367 ext. 3).
- **Manhattanville:** Sharps containers are removed by third party vendor **Stericycle**. Red bag waste (deposited in authorized containers) is removed by **Facilities Operations**. Requests for service are administered through Morningside Facilities Operations (212-854-2222).

More information in SEGREGATION AND DISPOSAL OF REGULATED MEDICAL WASTE section.

EXPOSURE DETERMINATION

The Standard requires a listing of all job titles/classifications where “occupational exposure” (see DEFINITIONS section) to Bloodborne Pathogens may exist. Since personal protective equipment (PPE) is considered a last line of defense, Columbia University policy is to conduct exposure determinations throughout the facility without regard to the use of PPE. Department Heads, Employee Supervisors and Principal Investigators (PIs) are responsible for identifying exposure risk among University staff. EH&S conducts, evaluates, and periodically reviews exposure determinations. This process involves identifying all the job classifications, tasks, or procedures in which employees have, or may have, occupational exposure to blood or OPIM. A representative list of these job classifications and tasks is provided in APPENDIX B. Staff performing these tasks are reviewed by medical providers during pre-employment and annual physicals, whereupon hepatitis B vaccination will be offered.

"Good Samaritan" acts which result in exposure to blood or other potentially infectious materials from assisting a fellow employee (i.e., assisting a co-worker with a nosebleed, giving CPR or first aid) are not covered by the *Bloodborne Pathogens Standard*. However, Post-Exposure Evaluation and Follow-up is provided in such cases. Those whose work location job description includes these activities are fully covered by *the Standard*.

The following sections, Engineering Controls, Work Practices, and Personal Protective Equipment, are the core guidelines for laboratory activities to minimize exposure risk. The specific details are discussed at length during EH&S-provided Bloodborne Pathogens Training sessions. Compliance in these areas is also monitored during regularly scheduled EH&S laboratory inspections and other EH&S laboratory-based activities.

ENGINEERING CONTROLS

Engineering Controls are devices or equipment that isolate or remove hazards, reducing the risk of infection. The following are several examples of engineering controls employed in and around University research areas.

Sharps Containers reduce the risk of accidental injury from discarded needles, slides, and other sharp objects. Improperly disposed needles are a major source of the approximately 600,000 needlesticks per year among health care workers⁽³⁾. Proper use of containers:

- Locate containers to facilitate the immediate disposal of used sharps.
- Do not overfill containers.
- At Medical Center and Manhattanville Campus laboratories, a contractor (Stericycle), supplies and collects sharps containers (and other receptacles; red bags) for regulated waste.
- At Morningside Campus, a contractor (Approved) hired through EH&S, supplies and collects sharps containers (and other receptacles; red bags).

Issues and requests for additional supplies should be addressed through EH&S and/or Facilities, not through the contractor (see PROGRAM ADMINISTRATION section).

“**Safe Needle Devices**” include *needleless systems* and *sharps with engineered sharps injury protection*, defined on pages 4 and 5. These devices allow for either the elimination of needles or automatic shielding of needles during clinical activities to reduce the risk of percutaneous injuries. The brochure, <http://www.cdc.gov/niosh/docs/2000-108/pdfs/2000-108.pdf> (page 10), provides information for “safe needles”. This is but one source that can be consulted to obtain information about “safe needle devices”. Safe needle devices are to be used whenever possible in clinical care environments and during the care and use of non-human primates.

Centrifuge Safety Devices prevent the release of infectious aerosols, particularly if a tube breaks during centrifugation. These devices include sealed rotors and safety cups - gasketed containers into which centrifuge tubes are placed. Please note, **plastic centrifuge tubes should be substituted for glass whenever possible.**

Biological Safety Cabinets (BSCs) reduce the risk of exposure to splashes and aerosols of potentially infectious materials; reference the University policy (<http://ehs.columbia.edu/BiosafetyCabinetsPolicy.pdf>). See the [EH&S Biosafety Manual \(section 2.3.1\)](#) for details on the safe use of BSCs.

Other engineering controls that may have applicability in reducing exposure risk include:

- Autoclaves
- “Bench-Kote”/other work surface coverings
- Spill Pans and Trays
- Mechanical Pipetting Devices
- Secondary Containers
- Specimen Transport Bags
- Splash Guards

OSHA regulations are subject to change in both their directive components and interpretative statements. EH&S will monitor, discuss during annual review of the plan and program, and communicate these changes to Principal Investigators and other personnel with oversight responsibilities for day-to-day operations by e-mail, distribution of printed material, and changes in the content of its Bloodborne Pathogen Training Program.

WORK PRACTICES

Work practice controls, also known as administrative controls, are modifications that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique). The following information refers to work practice controls that should be employed in all University settings involving potential bloodborne pathogen exposure.

- Use Standard Precautions (see DEFINITIONS section).
- Remove gloves when visibly contaminated and wash hands immediately after removal; wash other body parts as soon as possible after skin contact with infectious materials.
- Alcohol based hand rubs can be used for hand sanitization. This is particularly useful in areas where no hand washing facilities are immediately available. Wash with soap and water as soon as feasible.
- Do not pass sharps hand to hand; use a receiver or similar receptacle. Discard all used sharps into a sharps container at the point of use.
- Do not recap, break, or bend needles. Place all disposable sharps, including pipettes in the rigid “sharps” containers, never into a red bag.
- Handling, cleaning, and sterilizing reusable sharps, such as surgical instruments, must be performed with the utmost of caution. For example, using tongs or puncture resistant (armored) utility gloves is advised. Pre-soaking instruments in a disinfectant solution before cleaning will reduce (but not totally eliminate) infectious organisms on the instruments.
- Eating, drinking, smoking, application of cosmetics and handling contact lenses is prohibited in work areas. Food or beverages may not be stored in laboratory refrigerators/freezers.

- Perform operations with blood and OPIM in a manner that minimizes splattering and aerosol generation. When this is not possible, conduct such operations in a Biological Safety Cabinet (BSC). This includes filling tubes, and loading/unloading safety cups or rotors inside a BSC.
- Use secondary containers (durable transport containers, trays, specimen transport bags, or carts) to prevent leaks and spills during collection, handling, processing, storage, or transport of infectious materials.
- Decontaminate equipment prior to servicing or shipping. Items not completely decontaminated must bear a label noting the contaminated area.
- Use mechanical pipetting devices only; **do not mouth pipette**.
- Replace glass items with plastic ones; use pipettes or cannulas to aspirate liquids instead of needles.
- Inform non-laboratory personnel, outside contractors, etc. of the presence of infectious materials in the laboratory and ensure that their presence does not put them at risk of exposure.
- Maintain centrifuge rotor use logs and retire or derate rotors as per manufacturer's recommendations after a specified number of use hours at a given speed, time period, or total runs. For the highest speed centrifuges, ultracentrifuges, rotors must be "derated" (their maximum rpm reduced gradually over time) and then eventually retired after a period of continuous use. Inspect rotors for signs of corrosion and pitting; clean and disinfect with manufacturer-approved products that will not cause corrosion.
- Protect laboratory vacuum lines with liquid disinfectant traps and HEPA filters (see [EH&S Biosafety Manual \(section 2.3.2\)](#)).

Research laboratories (see DEFINITIONS section) must observe the following additional precautions:

- Limit laboratory access to authorized personnel;
- Keep doors closed when working with HBV, HCV, HIV, or other biosafety level-2 materials;
- Prepare a biosafety manual if this *ECP* does not cover all details;
- Conduct all work with blood or other potentially infectious material in a BSC or other containment device.
- The Regulated Medical Waste stream comprises of three routes; red bags, sharps containers and drain disposal. For more details refer to the [University's Regulated Medical Waste Policy](#). University policy requires that liquid waste that meets the definition of RMW (including blood and tissue culture media) must be chemically treated prior to drain disposal.
- Waste that contains cultures of Category A infectious substances must be treated on-site by autoclaving (solid or liquid) or chemically (liquid), prior to entering the Regulated Medical Waste stream. Waste that contains cultures of some Category B infectious substances (e.g. MRSA, *S. typhi*) must be treated on-site by autoclaving or chemically, prior to entering the Regulated Medical Waste stream. Please consult

EH&S (biosafety@columbia.edu) to determine whether a particular Category B infectious substance meets this requirement.

PERSONAL PROTECTIVE EQUIPMENT

Personal Protective Equipment (PPE) is provided at no cost to affected personnel and used whenever the potential for occupational exposure exists. **In most instances, the ‘baseline’ personal protective equipment consists of a lab coat, gloves, and eye protection for anyone working with potentially infectious materials.**

In addition to understanding the appropriate uses of various types of PPE, it is equally important to realize that all PPE items have limitations that should be considered in making a selection.

The “appropriateness” of PPE depends on the risk entailed in a particular operation, which in turn can be assessed by addressing the following questions:

When the identity of the infectious agent is known, what is its natural route of infection?

How hazardous is the agent, in terms of ease of transmissibility and severity of illness?

What are chances of accidental exposure for different types of activities?

Are needles or other sharp objects used, contributing to the risk of percutaneous injury?

If handling liquids, what is the likelihood of splashes or aerosols being created?

Gloves - Always inspect for holes and tears before donning. Gloves are subject to losing their “barrier protection” quality with prolonged use or as the result of exposure to laboratory chemicals. Change **disposable (“examination”) gloves** frequently during prolonged operations and as soon as possible if they become torn, or contaminated. **Disposable (“examination”) gloves** used for handling infectious materials do not provide protection against percutaneous injury. Never wash or attempt to decontaminate **disposable gloves** for reuse. **GLOVES MUST NOT BE WORN OUTSIDE OF THE LABORATORY**- materials leaving the laboratory should be contained/treated so that it is safe to transport them without wearing gloves. **Utility gloves** are recommended for cleaning and handling procedures where there may be a reasonable likelihood of tearing or puncture. They may be decontaminated for reuse if their integrity is not compromised. Discard them if they show signs of cracking, peeling, tearing, puncturing, or deterioration.

Glove selection - Gloves designed for barrier protection against bloodborne pathogens are not always the appropriate choice for handling hazardous chemicals. Manufacturers or laboratory supply companies furnish information on gloves that protect against hazardous chemicals. EH&S has collected links to several major manufacturers’ [guides for glove selection and use](#).

Latex allergies - Approximately 8% of health care workers have been sensitized to latex rubber proteins or the chemicals used in manufacturing the gloves⁽⁴⁾. EH&S can provide information on substitutes for latex gloves that provide the same level of barrier protection as latex without putting the wearer at risk for sensitization. Always use non-powdered gloves regardless of the glove material used. Latex proteins adsorbed onto airborne powder increase the risk of sensitization and can exacerbate pre-existing allergic symptoms.

Laboratory coats - Coats that fasten in the rear offer greater protection than front-fastening ones. If the potential exists for large amounts of splashing, a waterproof gown/apron that covers the neck and upper chest should be worn over a rear-fastened laboratory coat. Laboratory coats are not to be worn outside of the laboratory if they have been used while working with any potentially infectious material.

Eye protection - Safety glasses with side shields are the minimum eye protection for handling blood or other potentially infectious materials. They do not protect from large splashes. Splash-proof goggles, by virtue of their tighter fit around the eyes, are required for activities with an elevated risk of splash exposure. Face shields with a brow-bar, worn in conjunction with goggles are appropriate in the highest risk situations.

Surgical masks - provide protection against droplet/splash exposure of the nose and mouth. They do not provide a barrier to organisms transmitted by inhalation (e.g., tuberculosis). Masks in combination with eye protection devices such as safety goggles or glasses with solid side shields or chin-length face shields must be worn whenever splashes, spray, or droplets of blood or potentially infectious secretions/excretions can be reasonably anticipated during work when no engineering controls are in use.

Head and shoe covers – Footwear and head coverings are appropriate in situations where a high degree of splashing is anticipated, or in animal vivaria or procedure rooms.

Additional PPE precautions

The following additional practices should be observed with regards to personal protective equipment:

Remove PPE, **especially gloves**, before leaving the work area, and as soon as feasible after a garment becomes contaminated.

Place used disposable protective equipment in red bags for disposal. Reusable items (laboratory coats) should be kept, until removal for laundering, in labeled containers (see LABELS and SIGNS section)

If a garment(s) is contaminated by blood or other potentially infectious materials, it must be removed immediately or as soon as feasible. If a pullover scrub (as opposed to scrubs with snap closures) becomes minimally contaminated, employees should remove the pullover scrub in such a way as to avoid contact with the outer surface; e.g., rolling up the garment as

it is pulled toward the head for removal. However, if the amount of blood exposure is such that the blood penetrates the scrub and contaminates the inner surface, not only is it impossible to remove the scrub without exposure to blood, but the penetration itself constitutes exposure. Employees shall be trained to cut such a contaminated scrub to aid removal and prevent exposure to the face.

SEGREGATION AND DISPOSAL OF REGULATED MEDICAL WASTE

The Columbia University Regulated Medical Waste Policy (<http://ehs.columbia.edu/RMWpolicy.pdf>) provides comprehensive details on segregation and disposal. This section summarizes the content applicable to the OSHA BBP standard.

The following procedures apply to disposal of research-associated or clinical materials having the potential for causing disease or adverse health effects in humans. The *OSHA Bloodborne Pathogens Standard* uses the term, "regulated waste," to refer to the following categories of waste:

- Liquid or semi-liquid blood or other potentially infectious materials (OPIM)
- Items contaminated with blood or OPIM and which would release these substances in a liquid or semi-liquid state if compressed
- Items that are caked with dried blood or OPIM and are capable of releasing these materials during handling
- Contaminated sharps; and pathological and microbiological wastes containing blood or OPIM.

Discarded feminine hygiene products used to absorb menstrual flow do not fall within the definition of regulated waste. The intended function of products such as sanitary napkins is to absorb and contain blood. The absorbent material of which they are composed will, under most circumstances, prevent the release of liquid or semi-liquid blood or the flaking off of dried blood. These items must be discarded into waste containers that are properly lined with plastic bags. Such bags should protect the employees from physical contact with the contents.

At Morningside, sharps containers and regulated medical waste containers are provided by a Columbia-approved vendor, Approved. This service is coordinated by Environmental Health and Safety (212-854-8749), who should be contacted using a [chemical/hazardous waste pickup request](#) if additional empty containers are required, or if there are issues with the vendor.

At the Medical Center and Manhattanville Campus, “sharps” containers are provided and collected by Stericycle. Red plastic biohazard bags are provided and collected by Facilities Operations. Both services are coordinated by Facilities Operations (212-305-7367 ext. 3) who should be contacted if additional empty containers or bags are required. If there are issues with the vendor contact EH&S.

Regulated waste must be placed in containers that meet the following specifications:

- Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping.
- Labeled or color-coded in accordance with *the Standard* and marked prominently with the universal warning sign or the word “biohazard.”
- If outside contamination of the regulated waste container occurs, contaminated containers are placed in a second container meeting the above standards.
- Limit exposure to employees and the public. Each primary container holding regulated medical waste shall be located away from pedestrian traffic, be vermin and insect-free, and shall be maintained in a sanitary condition. Sharps containers in patient care areas are typically wall-mounted to reduce exposure likelihood.
- Closable. Sharps containers on the floor must be closable. Containers housing red bags in patient care areas must be kept closed with a lid; pedal bins are preferable. Containers housing red bags in areas where access is restricted, such as laboratories, do not require lids. However containers must be closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

Regulated medical waste may be held in patient care areas for a period not to exceed twenty-four (24) hours and at a clinical laboratory for a period not to exceed seventy-two (72) hours, at which time the waste shall be moved to a storage area. Sharps containers shall be removed from patient care areas to a room or area designated for regulated medical waste storage, whenever the container has reached the fill line indicated on the container. Sharps containers shall be removed from patient care areas within thirty (30) days or upon the generation of odors or other evidence of putrefaction, whichever occurs first, without regard to fill level.

Sharps containers must be used for disposal of the following items used in patient care or research activities: hypodermic needles, syringes, scalpel blades, tips, slides, cover slips, serological pipettes (glass or plastic), and blood vials. Essentially, any contaminated item that may tear a red bag during transport should be discarded in a sharps container. **Serological pipettes or pipette tips may not be disposed in red bags.**

Syringes and needles must never be separated and needles must never be recapped prior to disposal. Single use, disposable “vacutainer” tube holders are required for phlebotomy.

Sharps containers are available for the bench-top and in an 8 gallon size (floor model). Laboratories using large quantities of serological pipettes may request an 18-gallon container. Sharps containers must not be filled to the point where pipettes or other waste protrudes through the top; contact the respective Facilities Operations (at the Medical Center and Manhattanville Campus) or EH&S (at Morningside) to establish a pick-up schedule to prevent over-filling (see PROGRAM ADMINISTRATION, above).

Sharps containers must be easily accessible and located as close as feasible to the area(s) where sharps are used. They must be replaced routinely, closed when moved, and not overfilled. Never manually open, empty, or clean contaminated sharps containers.

The red plastic biohazard bags are to be used for “soft” items such as gloves and contaminated paper towels or other items that will not rip through the bag when it is picked up. Do not use red bags for “regular” trash (e.g., packing materials, papers, card board boxes, buffer/media bottles).

Red bags are always to be housed and transported in a rigid plastic container. When a red bag is ready for removal, the lab staff should tape it closed while it is within the rigid plastic container. In order to prevent injury from inadvertently disposed sharps, the container and bag are transported to the large gray bins (dumpsters) in the hallway, at which point the bag is lifted out of the container and placed in the large gray bin.

At Medical Center and Manhattanville, lab staff must place bags in the large gray bins in the hallway when available. At Morningside, containers are picked up on Tuesdays and Fridays by the University’s waste vendor. Laboratories are instructed to place their containers out “the morning of” instead of “the night before”, and are encouraged to bring the empties in as soon as possible. Unless these bins are cleaned and empty the lids must remain closed.

TRAINING

EH&S conducts [Bloodborne Pathogens training sessions](#) on a biweekly basis and when requested for an individual departments/groups. Personnel with potential occupational exposure must attend training **annually**. Refresher training is available online through the Research Compliance and Administration System (RASCAL) system. Task specific training is provided annually for Student Health Service staff and Facilities workers that transport RMW. Task-specific online training is provided for Athletics Department and Bard Gymnasium employees. Material is appropriate in content and vocabulary to the education level and literacy of the employees. PIs are responsible for ensuring that laboratory-specific training is provided at the point of hire and when changes in procedures or tasks may impact the safety of personnel. PIs performing basic research must complete a human materials Appendix C in RASCAL when their proposed research involves use or storage of human blood or OPIM, including primary tissue/cell cultures and cell lines (APPENDIX C). PIs performing studies reviewed by the IRB must complete a RASCAL attestation to affirm to a series of safety measures (APPENDIX D). Training programs will cover the following elements:

- An explanation of the requirements of the *OSHA Bloodborne Pathogens Standard*.
- An explanation of the epidemiology, transmission, and symptoms of bloodborne diseases.
- Information and where employees can obtain a written copy of the *Exposure Control Plan*.
- Methods that can be used to recognize and evaluate tasks and activities with potential exposure.
- An explanation of the use and limitations of the different methods of control including, but not limited to, engineering controls, work practices, and selection and use of protective equipment.

- Information on the appropriate actions and procedures to follow if an exposure occurs and details on the provision of post-exposure evaluation and medical consultation.
- Information on the Hepatitis B vaccine including efficacy, safety, method of administration, and that the vaccine will be free of charge to employees, based on job description, work location and EH&S risk assessment.
- An explanation of the signs and labels required by *the Standard*.
- An opportunity for interactive questions and answers. In an effective training program, it is critical that trainees have the opportunity to ask questions where material is unfamiliar to them. In a RASCAL-based program, this requirements is by providing an email link and telephone number so that trainees will have direct access to the biosafety office. OSHA believes that computer-based training programs can be used as part of an effective safety and health training program to satisfy OSHA training requirements, provided that the program is supplemented by the opportunity for trainees to ask questions of a qualified trainer, and Department Heads/Employee Supervisors/Principal Investigators (PIs) provide trainees with sufficient hands-on experience.

HEPATITIS B VACCINATION

Hepatitis B is a serious disease caused by a virus that attacks the liver. The virus, which is called hepatitis B virus (HBV), can cause lifelong infection, cirrhosis (scarring) of the liver, liver cancer, liver failure, and death. Transmission most commonly occurs via contact with infectious blood, semen, and other body fluids from having sex with an infected person, sharing contaminated needles to inject drugs, or from an infected mother to her newborn. Hepatitis B vaccination is recommended by the CDC for all infants, older children and adolescents who were not vaccinated previously, and adults at risk for HBV infection⁽²⁾.

The immunization series involves three intramuscular injections over a six-month period. The vaccine is effective > 95% of the time when all three doses are given and immunity is thought to be life-long once a titer has been demonstrated. It may be contraindicated for those with yeast allergy (the immunogenic antigen is cultivated in cells of *S. cerevisiae*); pregnant women should consult their physician before receiving the vaccine.

OSHA requires the use of CDC guidelines⁽²⁾ current at the time of the evaluation or procedure. Employees who do not respond to the primary vaccination series may elect to be re-vaccinated with a second three-dose series and re-tested. Non-responders must be medically evaluated.

The vaccination series must be offered, at no cost to employees, within 10 days of initial assignment for those with occupational exposure to blood or other potentially infectious materials unless:

- The employee documents previous completion of the series;
- Antibody testing reveals immunity; or,
- The vaccine is contraindicated for medical reasons.

Otherwise eligible personnel may decline the vaccination provided that they complete a Vaccine Notification Form. The University’s medical providers typically maintain these blank forms. Morningside, Manhattanville, Nevis and LDEO Campus personnel may elect to accept or decline vaccination using a RASCAL form (<https://www.rascal.columbia.edu/>) located in the Hazardous Materials menu. Completion of the Form acknowledges receipt of information on the advisability of receiving the vaccine and their right to receive it at any future date, at no cost to the employee. Completed Forms are maintained by the respective medical providers or within the RASCAL system (see PROGRAM ADMINISTRATION section)

Hepatitis B vaccines (and antibody testing) are administered to the employee by the applicable medical providers identified in the PROGRAM ADMINISTRATION section.

Determinations of employees with occupational exposure to blood borne pathogens, hence eligibility for hepatitis vaccination, are made by departmental administration in consultation with EH&S. Risk assessments are reviewed periodically based on:

- Employee job duties
- Shifting responsibilities; all staff may be called upon to perform various tasks in and around laboratory and clinical areas
- Employee work location
- Scope of research being performed in laboratories (use of human blood, primary cell lines)
- Findings of internal audits and external inspections by regulatory agencies
- Similar practices at peer institutions
- Interpretation of OSHA definition of “exposure potential”

Employee tasks and job classifications potentially at risk are listed in Appendix B.

EXPOSURE INCIDENTS

An exposure incident is defined as parenteral, non-intact skin or mucous membrane (e.g., eye, nose, mouth) contact with human blood or other potentially infectious materials. The determination that skin is intact, or not, should be made by the applicable medical provider.

Response summary

- Wash the wound
 - For percutaneous injuries, immediately cleanse the site with soap and water.
 - For mucous membrane exposures, rinse with water for 10 minutes.
- Seek immediate medical attention
 - Individuals exposed while on the Medical Center and Manhattanville campus should proceed to Workforce Health and Safety (WHS). During evenings, nights and weekends, individuals should go directly to the New York-Presbyterian Hospital Emergency Room and follow-up at WHS on the next business day.
 - Individuals exposed while on the Morningside campus should proceed to Workforce Health and Safety (WHS). During evenings, nights and weekends, individuals should go directly to the Mt. Sinai/St. Luke's-Roosevelt Hospital Emergency Room and follow-up at Health Services on the next business day
 - See PROGRAM ADMINISTRATION section for full information on facilities that provide the medical evaluations
- Report the incident
 - Notify your supervisor
 - Exposed individuals must complete a Columbia University Medical Center Departmental Accident Report (http://hr.columbia.edu/sites/default/files/document-files/2014/09/08/departement_accident_report.pdf).
- Participate in an investigation
 - A detailed assessment of the incident will be obtained to determine the risk of the exposure, including, if possible, the infectious status of the source and immune status of the exposed employee. This information will be used to determine the relative benefits of taking antiretroviral therapy and to offer counseling, treatment and tracking for other infectious agents.
 - EH&S investigates sharps injuries to perform root cause analysis and prevent recurrence. An accident report is provided to the exposed employee and their supervisor. The accident investigation template and list of questions that investigators ask is shown in APPENDIX E.

Response details

Guidelines for Post-Exposure Prophylaxis (PEP) call for treatment initiation, if warranted, within several hours⁽⁵⁾. An occupational exposure should be regarded as an urgent medical circumstance. The CDC's latest recommendations for anti-HIV post-exposure prophylaxis (2005) are included as APPENDIX A. Treatment with chemo prophylactic drugs is voluntary; they will be provided at no expense to those exposed in the course of their activities at the University.

Attempt to determine the source patient. If the source of exposure is an identifiable patient, bring the patient's name and medical record number, if known, when seeking treatment. As soon as possible, inform them of the exposure and obtain permission for blood drawing for testing (HBV, HCV, HIV). Blood tests for HBV and HCV will be ordered on the source patient and consent will be requested from the source patient for HIV testing. If the source

individual is already known to be HIV, HCV and/or HBV positive, new testing need not be performed.

In New York State, specific informed consent for HIV testing is required. Informed consent is not required for anonymous HIV testing of a person who is the source of an occupational exposure, who is deceased, comatose, or otherwise unable to provide consent, and no person authorized to consent on behalf of the source patient is immediately available, as provided in Public Health Law section 2781(6)(e).

- The results of the test shall not be disclosed to the source person or placed in the source person's medical record
(https://regs.health.ny.gov/sites/default/files/pdf/recently_adopted_regulations/2012-02-22_hiv-aids_testing.pdf).
- The results of such anonymous test, but not the identity of the source person, shall be disclosed only to the attending health care professional of the exposed person solely for the purpose of assisting the exposed person in making appropriate decisions regarding post-exposure medical treatment.
- Documentation that the source individual's test results were conveyed to the exposed employee's health care provider must be compiled and maintained.
- If the source individual has been determined and agreed to testing, the exposed employee must be provided with the source individual's test results and with information about applicable disclosure laws and regulations concerning the identity and infectious status of the source individual (e.g., laws protecting confidentiality).

After consent, an exposed employee's blood will be collected for baseline testing. If indicated, testing on a voluntary basis, for anti-HIV and anti-HCV antibodies will be conducted at six weeks, 12 weeks, six months, and twelve months. All test results are confidential and shared only with the tested employee.

Post-exposure counseling will be conducted. The counseling will address issues such as; refraining from blood, semen, or organ donation; abstaining from sexual intercourse or using measures to prevent HIV transmission during sexual intercourse; and refraining from breast feeding infants during the follow-up period.

In the event of an exposure incident, the incident will be investigated by EH&S with the laboratory supervisor or Principal Investigator, to determine:

- Routes of exposure and how the exposure occurred
- Engineering controls, work practices, and personal protective equipment used at the time
- Procedure being performed and type and brand of device(s) used when the incident occurred
- Employee's training status
- Department and/or location of the incident

The PI will, in cooperation with EH&S, as needed, make appropriate changes to the laboratory's Exposure Control Plan and operating procedures based on a review of the accident.

Although bloodborne pathogen exposure are typically treated in an ambulatory/outpatient setting, should an exposure require inpatient hospitalization, there are new OSHA requirements for the reporting of injuries (effective 1/1/15). Injuries must be reported within 24 hours. This could be by telephone to the OSHA toll-free central telephone number, 1-800-321-OSHA (1-800-321-6742), in person to the OSHA Area Office that is nearest to the site of the incident or by electronic submission using the reporting application located on OSHA's public Web site at www.osha.gov.

HOUSEKEEPING/CLEANING/DISINFECTION

Laboratories are required to implement a cleaning schedule for work surfaces (lab benches and equipment).

Cleaning Schedule

Work surfaces (lab benches and equipment) must be decontaminated immediately after a spill, at the end of procedures, and at the end of the day if the surface may have become contaminated during the course of the day.

A list of approved sterilants and disinfectants* can be obtained from the Environmental Protection Agency at <http://www.epa.gov/oppad001/chemregindex.htm> or by contacting EH&S.

*** Approved refers to a manufacturer's right to use terms such as "disinfectant", "tuberculocidal", "sporicidal", etc. on the product label, based on demonstrated anti-microbial activity in specified tests. A 10% solution of household bleach, prepared fresh daily, provides effective decontamination for routine housekeeping and spill response.**

A summary of disinfectant activities can be found in the [EH&S Biosafety Manual \(section 2.7.2.1\)](#)

Cleaning/Decontamination Procedures

- Always read manufacturers' label information concerning organisms inactivated, use procedures, and dilution; full strength products may be "hazardous chemicals" prior to dilution.
- Discard protective coverings such as plastic wrap and aluminum foil when contaminated.
- Regularly inspect and decontaminate reusable receptacles (bins, pails, and cans) that may have become contaminated. Decontaminate immediately upon noting visible contamination.
- Always use tongs, forceps, or a brush and dustpan to pick up broken glass, even when wearing gloves.

- Store or process reusable sharps in puncture-resistant containers.
- Place regulated medical waste in containers provided by Facilities Operations and/or the University's service vendor.

Laundry of PPE

Laboratory coats are provided to employees and are to be laundered at the employer's expense; they are never to be taken home for laundering. At Medical Center, the provision and laundering of laboratory coats is typically done on a department or laboratory basis; [Purchasing](#) can be contacted to obtain a list of vendors for this service. When handling contaminated articles for disposal or washing, wearers are to take the following precautions:

- Handle as little as possible and with a minimum of agitation;
- Be sure that all items have removed from pockets;
- Place articles in a bag or container labeled in accordance with "LABELS and SIGNS" section.
- Place wet laundry in a leak proof plastic bag.

Spill Response by lab staff, clinic staff or EH&S

- Alert people in immediate area of spill.
- Put on protective equipment (full-length lab coat, double gloves, eye protection, and shoe covers (if needed)).
- Cover spill with paper towel or other absorbent material; carefully pour a freshly prepared 1:10 dilution of household bleach (or other effective, properly diluted disinfectant) around the edges, working toward the middle.
- Allow a 20-minute contact period.
- Remove towels, using broom, tongs, dustpan, etc.-**never by hand**.
- Re-clean area with fresh disinfectant-soaked towels.

LABELS and SIGNS

Labels

Biohazard labels must be affixed to: containers of regulated medical waste; refrigerators and freezers containing blood and other potentially infectious materials; other containers used to store, or transport blood or other potentially infectious materials; contaminated equipment awaiting repair (note the area contaminated); and, laundry bags and containers. The warning label must be fluorescent orange or orange-red, contain the biohazard symbol and the word "BIOHAZARD" in a contrasting color, and be attached to each object by string, wire, adhesive, or other method to prevent loss or unintentional removal of the label.

Refrigerators and freezers containing blood or other potentially infectious material should have biohazard warning labels affixed to them in labs where diagnostic or other screening procedures are performed.

Labels, in a variety of sizes, are available by request from EH&S. The placement of labels is monitored during EH&S-conducted laboratory inspections.

These labels are not required when: red bags or red containers are used; individual containers of blood or other potentially infectious materials are placed in a labeled container during storage, transport, shipment or disposal; or, containers of blood, blood components, or blood products are labeled as to their contents and have been released for transfusion or other clinical use.

Signs

All laboratories covered by the *Bloodborne Pathogens Standard* and those working at Biological Safety Level-2 or higher must display: a BIOHAZARD sign at the entrance to the work area incorporating the features required for “Labels”, any special requirements for entering the area, and the name and campus office phone number of the PI or other responsible person. Doors of research laboratories engaged in the culture, production, concentration, experimentation, and manipulation of HIV and HBV must identify the agent on a door sign. Signs and door sign holders are available from EH&S.

RECORDKEEPING

Medical Records

In accordance with 29 CFR 1910.20, Workforce Health and Safety (WHS) maintains medical records for each Medical Center, Morningside Campus and Manhattanville employee with potential occupational exposure. The exception is that Health Services at Columbia maintains medical records for Athletics employees with potential occupational exposure.

In addition to other OSHA record keeping requirements, the medical record will include:

- The name and social security number of the employee;
- A copy of the employee’s Hepatitis B vaccinations, completed notification forms and any records relative to the employee’s ability to receive the vaccination;
- A copy of all results of examinations, medical testing, and follow-up procedures as required by *the Standard*; and,
- A copy of all healthcare professional’s written opinions as required by *the Standard*.

All employee medical records will be kept confidential and will not be disclosed without the employee’s express written consent to any person within or outside the workplace except as required by *the Standard* or as may be required by law.

Employee medical records shall be maintained for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.20.

Employee medical records shall be provided upon request of the employee or to anyone having written consent of the employee within 15 working days.

Hepatitis B vaccination acceptance/declination records

Depending on campus affiliation, WHS maintains these records for CUMC personnel and the RASCAL system maintains these records for the Morningside, Nevis and LDEO campuses.

Training Records

Training records will be maintained by EH&S. The records include: date(s) of training session(s); contents or a summary of the sessions; names and qualifications of persons conducting the training; and names and Department affiliation of all persons attending the training sessions. Training records will be maintained for a minimum of three (3) years from the date on which the training occurred. Employee training records will be provided upon request to the employee or the employee's authorized representative within 15 working days.

Training Certificates are available electronically to employees upon completion of training.

Incident Logs

Columbia University Medical Providers (see PROGRAM ADMINISTRATION section) maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log is recorded and maintained to protect the confidentiality of the injured employee. These activities are consistent with “safe needle” legislation enacted in November 2000. The sharps injury log shall note:

- The job classification of the exposed employee
- The department or work area where the exposure incident occurred
- The type of device and brand involved in the incident
- The body part injured
- The procedure being performed
- An explanation of how the incident occurred
- For sharps with engineered sharps injury protection (ESIP), if the safety mechanism was activated
- If the incident occurred before action, during activation or after activation of the mechanism; for sharps without engineered sharps injury protection, the employees opinion if ESIP could have prevented the injury.

No personal employee identifiers should be used in the Sharps Injury Log. The Sharps Injury Log is intended to serve as a tool for control of future incidents, not as a record of which employees have been injured. The Sharps Injury Log must be reviewed annually to identify patterns and special attention paid to injuries caused by sharps with and without ESIP. In these cases switching to sharps with ESIP or more effective ESIP should be considered. The Sharps Injury Log must be kept five (5) years from the date the exposure incident occurred. Cuts,

lacerations, punctures, and scratches are logged only if they are work-related and involve contamination with another person's blood or other potentially infectious material. If the cut, laceration, or scratch involves a clean object, or a contaminant other than blood or other potentially infectious material entry into the sharps injury log is not required. However such accidents should be investigated, and corrective actions implemented, to minimize the likelihood of recurrence.

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NYS HIV Clinical Guidelines Program <https://www.hivguidelines.org/pep-for-hiv-prevention/>

APPENDIX A

CDC Recommendations for anti-HIV Post Exposure Prophylaxis MMWR Sept. 30 2005

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5409a1.htm>

TABLE 1. Recommended HIV postexposure prophylaxis (PEP) for percutaneous injuries

Exposure type	Infection status of source				
	HIV-positive, class 1*	HIV-positive, class 2*	Source of unknown HIV status†	Unknown source§	HIV-negative
Less severe¶	Recommend basic 2-drug PEP	Recommend expanded ≥3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP** for source with HIV risk factors††	Generally, no PEP warranted; however, consider basic 2-drug PEP** in settings in which exposure to HIV-infected persons is likely	No PEP warranted
More severe§§	Recommend expanded 3-drug PEP	Recommend expanded ≥3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP** for source with HIV risk factors††	Generally, no PEP warranted; however, consider basic 2-drug PEP** in settings in which exposure to HIV-infected persons is likely	No PEP warranted

* HIV-positive, class 1 — asymptomatic HIV infection or known low viral load (e.g., <1,500 ribonucleic acid copies/mL). HIV-positive, class 2 — symptomatic HIV infection, acquired immunodeficiency syndrome, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of PEP should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up care for all exposures.

† For example, deceased source person with no samples available for HIV testing.

§ For example, a needle from a sharps disposal container.

¶ For example, solid needle or superficial injury.

** The recommendation "consider PEP" indicates that PEP is optional; a decision to initiate PEP should be based on a discussion between the exposed person and the treating clinician regarding the risks versus benefits of PEP.

†† If PEP is offered and administered and the source is later determined to be HIV-negative, PEP should be discontinued.

§§ For example, large-bore hollow needle, deep puncture, visible blood on device, or needle used in patient's artery or vein.

TABLE 2. Recommended HIV postexposure prophylaxis (PEP) for mucous membrane exposures and nonintact skin* exposures

Exposure type	Infection status of source				
	HIV-positive, class 1†	HIV-positive, class 2†	Source of unknown HIV status§	Unknown source¶	HIV-negative
Small volume**	Consider basic 2-drug PEP††	Recommend basic 2-drug PEP	Generally, no PEP warranted§§	Generally, no PEP warranted	No PEP warranted
Large volume¶¶	Recommend basic 2-drug PEP	Recommend expanded ≥3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP†† for source with HIV risk factors§§	Generally, no PEP warranted; however, consider basic 2-drug PEP†† in settings in which exposure to HIV-infected persons is likely	No PEP warranted

* For skin exposures, follow-up is indicated only if evidence exists of compromised skin integrity (e.g., dermatitis, abrasion, or open wound).

† HIV-positive, class 1 — asymptomatic HIV infection or known low viral load (e.g., <1,500 ribonucleic acid copies/mL). HIV-positive, class 2 — symptomatic HIV infection, AIDS, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of PEP should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up care for all exposures.

§ For example, deceased source person with no samples available for HIV testing.

¶ For example, splash from inappropriately disposed blood.

** For example, a few drops.

†† The recommendation "consider PEP" indicates that PEP is optional; a decision to initiate PEP should be based on a discussion between the exposed person and the treating clinician regarding the risks versus benefits of PEP.

§§ If PEP is offered and administered and the source is later determined to be HIV-negative, PEP should be discontinued.

¶¶ For example, a major blood splash.

APPENDIX B

Tasks or procedures in which “occupational exposure” might occur include:

- Work with the following materials:
 - Human or non-human primate blood
 - Other Potentially Infectious Materials (OPIM) - (1) The following human/ non-human primate body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and (3) HIV containing cell or tissue cultures, organ cultures, and HIV or HBV containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.
 - Human or non-human primate cell lines (regardless of being declared "pathogen-free")*. Includes work with viral vectors in human/non-human primate cell lines or introduction of human cells or cell lines into experimental mammals.
 - Infectious agents that can cause disease in healthy human subjects
- Work with non-human primates
- Participation in human research studies that may entail blood/body fluid exposure.
- Clinical activities with the potential for exposure to blood or body fluids that may contain bloodborne pathogens.
- Activities related to teaching or demonstrating bloodletting.
- Responsibility for processing surgical and other instruments that may be contaminated with materials containing bloodborne pathogens.
- Administration of first aid by athletic trainers, physical therapists and gym personnel.
- Laundering of blood-soaked athletic wear and towels.
- Removal/transport of Regulated Medical Waste from University laboratories and other work sites.

Job Classifications in which employees may have occupational exposure

Medical Center, Zuckerman Institute, Nevis Labs and Lamont Doherty Earth Observatory Personnel

- Student Health Services clinical staff
- Schools of Medicine, Dentistry, Nursing, Physical therapy and Occupational Therapy
 - Clinicians
 - Faculty and staff that teach clinical procedures
- Clinical Laboratory workers
- Faculty and staff that perform laboratory research with the materials listed above, or non-human primates
- Facilities Operations
 - Custodial Personnel that transport RMW

- Custodial Personnel that service Student Health Services
- Bard Gym Personnel that do laundry and administer first aid

Morningside Personnel

- Health Sciences Center (Student Health) clinical staff
- Faculty and staff that perform laboratory research with the materials listed above
- Intercollegiate Athletics and Physical Education –
 - Team Physician
 - Athletic Trainer
 - Laundry staff, including work-study students
 - Head Coaches
 - Assistant Coaches (Full & Part-Time)
 - Volunteer Assistant Coaches
 - Personal trainers
 - Group Fitness Instructors

APPENDIX C

Human Materials (Appendix C)

Appendix Number		Subject Species	n/a
Title			
Creation Date		Initiator	
You are		Appendix Released	No

NOTE:Principal investigators **MUST** complete Appendix C when proposed research involves use or storage of human blood or OPIM, including *primary* tissue/cell cultures and cell lines. Contact Environmental Health & Safety at 212-305-6780 or 212-854-8749 or visit <http://www.ehs.columbia.edu> if you have questions or need assistance.

- Use of human materials (blood, body fluids, tissues, cells)** Invitro/Invertebrates only
 Used/Administered as part of an IACUC or IRB protocol.

Project Title: Description of activities/goals

Human materials used/administered to

Are there any relevant vaccinations or work restrictions/considerations (immune status, pregnancy) that should be acknowledged?

Personnel with exposure to human blood, unfixed tissues or cell lines must be offered the Hepatitis B vaccine and be current on Biosafety/Bloodborne Pathogens training. See <http://www.ehs.columbia.edu/Training.html> for training requirements and scheduling.

Have affected staff been informed of vaccine availability and training requirements? (MUST ANSWER) Yes No

**BLOODBORNE PATHOGENS EXPOSURE
CONTROL PLAN**

**Procedure: 2.13 Version: 6.6
Revised: 03/10/2017**

1. List names of all human material(s) (blood, body fluids, cell lines) that are being used or stored in your laboratory.

2. Laboratory location(s) where work with human material(s)/cell(s) will take place. Include all Lab sites for in vitro work and if applicable, sites where infectious materials will be administered to animals.(see "Locations" Page))

3. Operational safeguards for laboratory manipulations

a. Engineering control to be used (e.g., biological safety cabinet -indicate location and certification date ; safety cup for centrifugation; etc.) (Biological safety cabinets must be certified annually)

b. Personal protective equipment(PPE) to be used. Gloves, lab coats and eye protection/safety glasses are the minimum requirements. Select specific PPE to be used below.

- | | |
|--------------------------------------|---|
| <input type="checkbox"/> Face Shield | <input type="checkbox"/> Respirators* |
| <input type="checkbox"/> Gloves | <input type="checkbox"/> Safety Glasses |
| <input type="checkbox"/> Goggles | <input type="checkbox"/> Shoe Covers |
| <input type="checkbox"/> Head Covers | <input type="checkbox"/> Surgical/Dusk Mask |
| <input type="checkbox"/> Lab Coats | |

***The proper use of engineering controls and appropriate work practices should eliminate the need for respirator use. If required, respirator use must be preceded by medical clearance, and formal training and fit testing. If you believe your activities require respirator use, contact your campus EH&S office.**

Please add other Personal Protective Equipment NOT part of the list above.

4. Emergency procedures

a. In the event of overt personal exposure



Wash exposed skin with soap and water; for eye/face exposures use eye wash. Report to Workforce Health and Safety or Student Health Services. During nights and weekends, go to NYP (CUMC) or St. Lukes-Roosevelt (Morningside) Emergency Room.

Confirm all staff familiar with personal exposure response.(MUST ANSWER) Yes No

b. For spills/releases, treat the contaminated area with 10% household bleach solution (freshly prepared daily) for 20 minutes and then clean it up. Dispose of all solid waste as Red-Bag Waste.

Conform all staff familiar with spill/accident response Yes No

c. If you will use disinfectants or procedures other than recommended, please specify

5. Research staff must observe the following Regulated Medical Waste disposal procedures.



- **Dispose of syringes/needles (without separation), serological pipettes (glass or plastic) glass Pasteur pipettes, and other sharps in a sharps container.**
- **Dispose of all other potentially infectious waste in red bags.**
- **It may be necessary to autoclave waste of certain infectious agents before disposal as red bag waste. EH&S will determine if autoclaving is necessary as part of the evaluation of this document.**
- **All containers must have the PI name & room No.**

If you will use the human material(s) listed in No. 1 in research animals, complete 6, 7, & 8.

6a. Animal specie

b. Route of administration to animal:

c. To what extent, if any, will viable materials be shed into the environment by way of feces, urine, open skin lesion, exhalation, saliva, or nasal secretions?

7. Please describe briefly experimental protocols for animal use (including number of animals, concentration, frequency , and route of administration.)

8. Operational safeguards for subject use

a. Engineering controls to be used (e.g., biological safety cabinet, subject isolation/housing. If a biological safety cabinet will NOT be used to administered infectious material, briefly note how work surfaces will be protected from contamination and subsequently disinfected and how personal exposure will be minimized.)

b. Personal protective equipment (PPE) to be used. Gloves, lab coats and eye protection/safety glasses are the minimum requirements. Note any additional PPE to be used.

- | | |
|--------------------------------------|---|
| <input type="checkbox"/> Face Shield | <input type="checkbox"/> Respirators* |
| <input type="checkbox"/> Gloves | <input type="checkbox"/> Safety Glasses |
| <input type="checkbox"/> Goggles | <input type="checkbox"/> Shoe Covers |
| <input type="checkbox"/> Head Covers | <input type="checkbox"/> Surgical/Dusk Mask |
| <input type="checkbox"/> Lab Coats | |

***The proper use of engineering controls and appropriate work practices should eliminate the need for respirator use. If required, respirator use must be preceded by medical clearance, and formal training and fit testing. If you believe your activities require respirator use, contact your campus EH&S office.**

Please add other Personal Protective Equipment NOT part of the list above.

9. Observe the following Regulated Medical Waste disposal procedures for animal-related activities.

- Decontaminate work surfaces with 10% household bleach solution (***freshly prepared daily***) or equivalent product.
- Dispose of syringes/needles (***without separation***) and other sharps in a sharps container.
- Dispose of all infected animal carcasses and body parts in red bags.
- Dispose of animal bedding in red-bags.

APPENDIX D

Attestation

Top of Form

Protocol Number		IRB-AAAA2552	
Date Created		Department	
Principal Investigator		Initiator	
You are		Year	

The selection of [**Analysis of Existing Biological Specimens**] as being applicable to the proposed research requires that the Principal Investigator affirm that the following safety measures are/will be in effect for the activities described.

Training, equipment and standard operating procedures:

- All protocol staff have undergone Bloodborne Pathogens / Biosafety training* within the last year of the date of this submission, and have undergone/will undergo task-specific training for all activities described in the protocol
- All engineering control devices used in conjunction with the protocol, including, but not limited to biosafety cabinets and chemical fume hoods, are currently certified and properly maintained**
- All staff are trained in the appropriate response to release of, or exposure to, protocol-related hazardous materials.
 - All spills will be treated/cleaned with a freshly-prepared bleach solution or other appropriate disinfectant.
 - Medical attention will be sought in the event of an exposure at Workforce Health and Safety or the NY Presbyterian Hospital Emergency Room
- All regulated medical waste will be disposed of in accordance with applicable regulations
 - All research-associated materials will be discarded in red bags
 - All sharps, including serological pipettes and micropipette tips will be discarded in rigid sharps containers.
- Personal protective equipment will be made available and used at all times during protocol activities involving potential exposure to blood or OPIM. At a minimum, PPE will include gloves, lab coats and protective eyewear.
- All CU and NYPH employees potentially exposed to blood or OPIM during the activities associated with this protocol are enrolled in an occupational surveillance program at Workforce Health & Safety and have been offered the Hepatitis B vaccine.
- Shipping of materials defined as "Dangerous Goods" by the US Department of Transportation of international regulations will be done by properly trained individuals.

(Information on the applicability of shipping regulations can be found at <http://www.ehs.columbia.edu/transport.html>. If required, training courses are available on RASCAL. NOTE: Dry Ice is considered a Dangerous Good for shipping purposes and those involved in its shipment must be trained.)

For all protocols involving human gene transfer, please contact EH&S directly at 212-305-6780.

*** Training options:**

For exposure to human blood, tissue, and other potentially infectious body fluids primarily in clinical settings, completion of the RASCAL course TC0025 will fulfill the training requirement. For exposures primarily in research lab settings, either classroom training or RASCAL course TC0509 can be taken. EH&S training schedules can be found at: <http://www.ehs.columbia.edu/Training.html>

****** The preceding applies to individuals and facilities under the direct physical control/supervision of the Principal Investigator. For off-site activities, including independent laboratory analysis and field studies, Principal Investigators are strongly encouraged to obtain reasonable assurance that all protocol-related activities are compliant with applicable laws and regulations.

I acknowledge and accept responsibility for the safe conduct of research involving the aforementioned hazardous materials.

Hit CERTIFY button only ONCE to complete disclosure.

APPENDIX E

COLUMBIA UNIVERSITY Environmental Health and Safety http://ehs.columbia.edu/

Medical Center: 630 W. 168th Street, Box #8 New York, NY 10032 Tel: 212-305-6780

Morningside Campus: 419 W. 119th Street, Mail Code 2215 New York, NY 10027 Tel: 212-851-8749

ACCIDENT INVESTIGATION CONFIDENTIAL - DO NOT DISTRIBUTE

EHS INVESTIGATION

Accident Report No. [redacted] Report Status: OPEN [dropdown]
EHS Investigator: [redacted]
Investigation Started: [redacted] Completed: [redacted]
Report Distribution List: [redacted]

EMPLOYEE INFORMATION

Last Name: [redacted] First Name: [redacted]
Employee ID/UNI: [redacted] Phone: [redacted]
Department: [redacted] Job Title: [redacted]
Supervisor: [redacted]

ACCIDENT INFORMATION

Date of Accident: [redacted] Date Reported: [redacted]
Building: [redacted] Location: [redacted]
Description: [redacted]

INVESTIGATION

[Large redacted area for investigation details]

ROOT CAUSE

[Redacted area for root cause]

RECOMMENDATIONS/ CORRECTIVE ACTIONS

[Redacted area for recommendations and corrective actions]

Printed on: [redacted]

Created: July 2015

Questions to ask when investigating needlestick or sharps accidents

Last name
 First name
 UNI
 CU Department
 Occupation
 Work phone
 Name of supervisor
 Date of injury
 Location where injury occurred
 What were you doing at the time of the accident?
 Type of procedure
 What kind of sharp were you working with?
 Needle/scalpel/microtome etc.
 Make/model?
 Sharp with engineered safety feature?
 If so, did the incident occur before action, during activation or after activation of the safety mechanism?
 If not, is using an engineered sharp possible in your work practices to replace currently used sharps?
 How did the accident occur?
 Were you performing the procedure at the time of the accident?
 Were you disposing/recapping the sharp at the time of the accident?
 Was there a sharps container close to where you were working?
 Was the sharp clean or used?
 What was the nature of the material in/on the sharp?
 Patient specimen/blood/OPIM/infectious material
 Recombinant DNA/viral vector
 Chemical agent
 What kind of injury did you sustain?
 Scratch/puncture/laceration
 Description of body part/injury site
 Were there any contributing factors?
 Tired/fatigued/distracted/in a hurry?
 Inadequate sedation of animal/did the animal move?
 What PPE were you wearing?
 Gloves/armored gloves
 What did you do immediately following the incident?
 Wash the wound?
 Notify supervisor
 Medical evaluation
 Which provider (student health/WHS/ER)
 If at the ER, did you follow up with WHS or Student Health, ASAP or the next day?
 What would you do differently in the future to avoid having the same accident?
 Do you need to take any further action to close out this accident?
 Would you like us to follow up with any additional information?
 Is the incident considered closed by EH&S?
 Was the SOP followed when injury occurred?