



EXPOSURE CONTROL PLAN



**Office of Environmental Health and Radiation Safety
(EHRS)**

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UNIVERSITY of PENNSYLVANIA EXPOSURE CONTROL PLAN

I. Introduction

Certain job activities at the University of Pennsylvania may result in occupational exposure to human blood and other body fluids that have the potential for carrying infectious agents. The Exposure Control Plan describes mechanisms for compliance with the Occupational Safety and Health Administration (OSHA) standard, "[Occupational Exposure to Bloodborne Pathogens; Final Rule](http://www.osha-slc.gov/needlesticks/needlesticks-regtxtrev.html)", 29 CFR Part 1910.1030, rev. 2001, (<http://www.osha-slc.gov/needlesticks/needlesticks-regtxtrev.html>), to ensure worker safety and environmental protection.

Tuberculosis

In 1994, the Centers for Disease Control and Prevention (CDC) published the "[Guidelines for preventing the Transmission of *Mycobacterium tuberculosis* In Health-Care Settings, 1994](http://www.hc-sc.gc.ca/pphb-dgsp/msds-ftss/msds103e.html)". The guidelines made specific recommendations for reducing the risk of transmitting *Mycobacterium tuberculosis* (<http://www.hc-sc.gc.ca/pphb-dgsp/msds-ftss/msds103e.html>) in healthcare settings as a result of the increase of tuberculosis outbreaks in the United States during the mid-1980s and early 1990s. They contain specific information on ventilation requirements, respiratory protection, medical surveillance and training for those personnel who are considered at risk for exposure to tuberculosis in the workplace.

In December 2005, the guidelines were reevaluated and changes were made. The "[Guidelines for preventing the Transmission of *Mycobacterium tuberculosis* In Health-Care Settings, 2005](http://www.hc-sc.gc.ca/pphb-dgsp/msds-ftss/msds103e.html)" were made available highlighting specific changes from the previous guidelines. Recommendations are summarized in Appendix D of this plan. ***If employees are at-risk of exposure to tuberculosis, the PRINCIPAL INVESTIGATOR/AREA SUPERVISOR must review the recommendations in Appendix D and ensure that they are in effect in their area.***

Investigators intending to work with *Mycobacterium tuberculosis* in the laboratory must obtain written approval from EHRS **before** beginning work. Propagation and manipulation of *Mycobacterium tuberculosis* cultures must be performed at Biosafety Level 3. A complete description of Biosafety Level 3 may be found in the [University's Biological Safety Manual](http://www.ehrs.upenn.edu/programs/bio/bio_manual.html) (http://www.ehrs.upenn.edu/programs/bio/bio_manual.html)

For more information consult the [CDC's TB Facts for Health Care Workers](http://www.cdc.gov/nchstp/tb/faqs/tbfacts/default.html) (<http://www.cdc.gov/nchstp/tb/faqs/tbfacts/default.html>) or call EHRS at 215-898-4453.

Bloodborne Pathogens

In accordance with the OSHA Bloodborne Pathogens standard, 29 CFR 1910.1030, rev. 2001, the University of Pennsylvania developed an exposure control plan to minimize occupational exposure to bloodborne pathogens such as Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV). ***The PRINCIPAL INVESTIGATOR/AREA SUPERVISOR must complete bold italicized portions of this plan (see Appendix C) and make the completed plan accessible to all employees who work with human blood, blood products or other potentially infectious materials in their area.***

Copies of this plan are available at the EHRS web site (www.ehrs.upenn.edu) or from:

**EHR
Suite 400
3160 Chestnut Street/6287
215- 898- 4453**

II. Bloodborne Pathogens Exposure Control Plan

The following plan establishes practices and procedures for employees who work with human blood and other potentially infectious materials:

A. Definitions

Blood- human blood, human blood components and products made from human blood. Human blood components include plasma, platelets and serosanguinous fluids (e.g., wound exudates).

Bloodborne pathogens- any pathogenic microorganisms that may be present in human blood and can cause human disease. These pathogens include but are not limited to HIV and HBV. Other bloodborne pathogens include agents of hepatitis C, malaria, syphilis, babesiosis, brucellosis, leptospirosis, arboviral infections, relapsing fever, Creutzfeld-Jakob disease, Human T-lymphotrophic Virus type I and viral hemorrhagic fever.

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

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 infectious particles and the surface or item is rendered safe for handling, use or disposal.

Employee- any permanent or temporary employee, graduate or undergraduate student that receives a University paycheck and could potentially be exposed to bloodborne pathogens in the course of their work.

Engineering controls- controls (e.g. sharps disposal containers, self-sheathing needles) 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, abrasions, chafing, etc.

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

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

Other potentially infectious materials- (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); (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.

Needleless systems- a device that does not use needles for (1) the collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established; (2) the administration of medication or fluids; or (3) any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

Parenteral- piercing mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts and abrasions.

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

Regulated waste- 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.

Sharpⁱ with engineered sharps injury protection- a non-needle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.

Source individual- any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee.

Standard precautionsⁱⁱ (formerly universal precautions)- an approach to infection control in which all human blood and human body fluids, secretions and excretions except sweat are treated as if they are infected with 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).

B. Exposure Determination

OSHA requires employers to determine which employees may incur occupational exposure to blood or other potentially infectious materials. The exposure determination is made without regard to the use of personal protective equipment (i.e. employees are considered to be exposed even if they wear personal protective equipment). This exposure determination is required to list all job classifications in which all employees may be expected to incur such occupational exposure, regardless of frequency. At PENN the following job classifications are in this category:

(SEE Appendix A)

In addition, OSHA requires a listing of job classifications in which some employees may have occupational exposure. Not all employees in this category would be expected to incur exposure to blood or other potentially infectious materials. Therefore, to clearly understand which employees in this category are considered to have occupational exposure, specific tasks or procedures that may cause occupational exposure in each job classification must be listed. The job classifications for this category are as follows:

(SEE Appendix B)

The PRINCIPAL INVESTIGATOR/AREA SUPERVISOR must complete Appendix C, #1 and #2, as follows:

#1. The PRINCIPAL INVESTIGATOR/AREA SUPERVISOR shall identify additional job classifications in their area in which employees are exposed if they are not listed in Appendix A or B. This assessment will be made without accounting for the use of personal protective equipment.

#2. For those jobs classifications in which some employees may have occupational exposure to blood or bloodborne pathogens (Appendix B), the PRINCIPAL INVESTIGATOR/AREA SUPERVISOR will list those associated tasks or procedures that would cause employees to have potential occupational exposure.

C. Implementation Schedule and Compliance Methods

1. The following is PENN's implementation schedule:

Exposure Control Plan	May 5, 1992
Communication of Hazard (training, signs and labels)	June 4, 1992
Record keeping (medical and training)	June 4, 1992
Methods of Compliance	July 6, 1992
Hepatitis B Immunization, post exposure evaluation and follow-up	July 6, 1992
HIV/HBV Research Labs	July 6, 1992
(Facility Criteria, Animal Facility Criteria, and Special Criteria)	
Additional training	June 4, 1992
Needlestick and Other Sharps Injuries, Final Rule	July 18, 2001

ⁱ **Sharps** are devices/items having corners, edges, or projections capable of cutting or piercing the skin. This includes hypodermic needles, syringes (with or without the attached needle), pasteur pipettes, scalpel blades, blood vials, needles with attached tubing, culture dishes, suture needles, slides, cover slips and other broken or unbroken glass or plasticware. Sharps must be managed in accordance with the [EHRS Laboratory Sharps Waste Management Procedure](http://www.ehrs.upenn.edu/resources/waste/bio/usedsharps.html) (<http://www.ehrs.upenn.edu/resources/waste/bio/usedsharps.html>).

ⁱⁱ In 1996 the Centers for Disease Control and Prevention replaced "universal precautions" with "standard precautions". See "Guideline for Isolation Precautions in Hospitals", JS Garner et al, Inf. Cont & Hosp. Epid., Vol. 17, No.1, p 53-80, Jan., 1996.

2. Compliance Methods

- a. **Standard Precautions**, formerly called **Universal Precautions**, (<http://www.cdc.gov/ncidod/hip/Blood/UNIVERSA.HTM>) will be observed in order to prevent contact with blood or other potentially infectious materials. Employees shall practice standard precautions and be trained in decontamination techniques *prior* to handling any blood or other potentially infectious materials. All blood or other potentially infectious materials will be considered infectious regardless of the perceived status of the source individual.
- b. **Engineering and work practice controls** will be utilized to eliminate or minimize exposure to employees at this facility. Additional information on engineering and work practice controls may be found in the [University's Biological Safety Manual](#), available at the EHRS web site (http://www.ehrs.upenn.edu/programs/bio/bio_manual.html) or from EHRS. Personal protective equipment will be utilized to further reduce occupational exposure.

1) The following **engineering controls** will be utilized:

- i. **Biological safety cabinets** (<http://www.ehrs.upenn.edu/programs/bio/cleanbench.html>) provide containment of infectious aerosols; isolate the operator from the agent; protect other personnel in the room. Cabinets must be certified annually or whenever moved. Contact EHRS (ehrs@ehrs.upenn.edu) for assistance with cabinet selection and proper placement in the laboratory.
- ii. **Sharps containers** must be used for disposal of all needles, syringes and other sharps. Disposable sharps shall be separated from reusable sharps at the time of their disposal. All sharps shall be placed in an appropriate sharps container immediately or as soon as possible after use. Place sharps containers as near to procedure area as possible.

Sharps containers must be non-breakable, puncture resistant, leak proof, sealable and labeled with the universal biohazard symbol. Filled sharps containers will be removed for decontamination and cleaning by designated personnel in each department. Sharps containers must be replaced periodically when they are 2/3-3/4 full. For more details, consult the [EHRS Laboratory Sharps Waste Management Procedure](#) (<http://www.ehrs.upenn.edu/resources/waste/bio/usedsharps.html>).

Reusable syringes and needles and other sharps must be placed in a separate container filled with disinfectant prior to decontamination and cleaning. To eliminate sorting later, do not place reusable sharps in pans containing pipettes or other glassware.

- iii. **Mechanical pipetting devices** must be used. Mouth pipetting is prohibited.
- iv. **Sharps with engineered sharps injury protection and needleless systems** are recommended. University personnel evaluate devices for effectiveness in reducing the risk of exposure incidents. Contact EHRS at (215) 898-4453, refer to the [Safety Engineered Sharps Evaluation Program](#) at the EHRS website (<http://www.ehrs.upenn.edu/programs/bio/sharps.html>), and/or see Appendix G of this Exposure Control Plan for more information.
- v. **Splash guards and plastic backed absorbent pads** must be used to contain the spread of blood and potentially infectious material in the laboratory.
- vi. **Sealed rotor heads and centrifuge cups** are used to avoid accidental spills and are an integral part of routine centrifuge operation.

The above controls will be examined and maintained on a regular schedule. **The schedule for reviewing the effectiveness of engineering controls is the responsibility of the PRINCIPAL INVESTIGATOR/AREA SUPERVISOR.** Contaminated equipment (biosafety cabinets, mechanical pipetting devices, splash guards, etc.) must be decontaminated at the end of the workday or after a spill.

2) **Work practice controls** are modifications of work procedures to reduce the likelihood of occupational exposure to blood or other potentially infectious materials. At PENN the following **work practice controls** will be utilized:

- i. **Hand washing:** Hand washing facilities must be readily accessible to all employees who incur exposure to blood or other potentially infectious materials. Hand washing facilities are located in laboratories and clinical areas.

If hand washing facilities are not readily available, the *PRINCIPAL INVESTIGATOR/AREA SUPERVISOR* is required to provide either an antiseptic cleanser in conjunction with clean cloth/paper towels or antiseptic towelettes. If these alternatives are used then the hands are to be washed with soap and running water as soon as feasible. The "CDC Guidelines for Hand Hygiene" can be found at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5116a1.htm>

After removal of personal protective gloves, employees shall wash hands & any other potentially contaminated skin areas immediately or as soon as feasible with soap & water.

If employees incur exposure to their skin or mucous membranes, those areas shall be washed or flushed with water as appropriate as soon as feasible following contact.

- ii. **Sharps/Needles:** Contaminated needles and other contaminated sharps will not be bent, recapped, removed, sheared or purposely broken. If a medical procedure requires that the contaminated needle be recapped or removed and no alternative is feasible, the recapping or removal of the needle must be done by the use of a mechanical device or a one-handed scoop method. Contact EHRS (ehrs@ehrs.upenn.edu) for alternative methods. Mixed waste sharps contaminated with carcinogens or mutagens must be separated from other sharps. These sharps must be discarded in an approved sharps container, labeled "**Carcinogen Contaminated Sharps / Do Not Autoclave**" and removed with other autoclaved infectious waste.

Sharps contaminated with radionuclides must be separated from other sharps.

All sharps must be discarded in an approved sharps container in accordance with guidelines described in the [EHRS Laboratory Sharps Waste Management Procedure](http://www.ehrs.upenn.edu/resources/waste/bio/usedsharps.html) (<http://www.ehrs.upenn.edu/resources/waste/bio/usedsharps.html>).

- iii. **Work Area Restrictions:** In work areas where there is a reasonable likelihood of exposure to blood or other potentially infectious materials, employees shall not eat, drink, apply cosmetics or lip balm, smoke, or handle contact lenses. Food and beverages are not to be kept in refrigerators, freezers, shelves, cabinets, or on counter tops or bench tops where blood or other potentially infectious materials are present.

Mouth pipetting / suctioning of potentially infectious materials is prohibited.

All procedures will be conducted in a manner that will minimize splashing, spraying, splattering, and generation of droplets of blood or other potentially infectious materials. **The PRINCIPAL INVESTIGATOR/AREA SUPERVISOR is responsible for identifying methods that will be employed in their areas. (Complete Appendix C, # 3.)**

- iv. **Specimen Handling and Transport:** Blood or other potentially infectious materials will be placed in a container that prevents leakage during the collection, handling, processing, storage, and transport of the specimen.

The container used for this purpose will be labeled or color coded in accordance with the requirements of the OSHA bloodborne pathogens standard and will be closed prior to handling. In order to qualify for an exemption to this requirement, standard precautions shall be practiced in the handling of all specimens. This exemption shall apply only while specimens remain at PENN.

Any specimens that could puncture a primary container will be placed within a puncture-resistant secondary container. ***The PRINCIPAL INVESTIGATOR/ AREA SUPERVISOR shall specify how this will be carried out, i.e. which specimens, if any, could puncture a primary container, which containers may be used as secondary containers and where the secondary containers are located in their area. (Complete Appendix C, # 4.)***

If outside contamination of the primary container occurs, the primary container shall be placed within a secondary container which prevents leakage during the handling, processing, storage, transport, or shipping of the infectious agent (which are considered Dangerous Goods).

All shippers of infectious material must attend biennial training to fulfill regulatory requirements. For details, call EHRS at (215) 898-4453 or consult the [EHRS website](http://www.ehrs.upenn.edu/programs/bio/transporting.html) (<http://www.ehrs.upenn.edu/programs/bio/transporting.html>).

- v. **Contaminated Equipment:** Equipment which has become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary unless the decontamination of the equipment is not feasible.

The PRINCIPAL INVESTIGATOR/AREA SUPERVISOR shall list any equipment that cannot be decontaminated prior to servicing or shipping. (Complete Appendix C, # 5.)

The PRINCIPAL INVESTIGATOR/AREA SUPERVISOR must contact the shipper or service provider to obtain their labeling requirements prior to shipping or servicing of contaminated equipment.

- vi. **Personal Protective Equipment:** [OSHA standard 29 CFR 1910.132](http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9777&p_text_version=FALSE) (http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9777&p_text_version=FALSE) requires workplace assessment for potential hazards and mandates that employers provide appropriate personal protective equipment (PPE) for employees. Investigators or area supervisors are responsible to perform the assessments and to select and train employees in the use of routine items such as lab coats, protective gloves, safety glasses, face shields, etc. Investigators or area supervisors must consult with EHRS for assistance with the selection and training of employees for the use of non-routine PPE such as respirators.

Personal protective equipment shall be provided without cost to all employees who are at risk of occupational exposure to bloodborne pathogens. Personal protective equipment will be chosen based on the anticipated exposure to blood or other potentially infectious materials. The protective equipment will be considered appropriate only if it does not permit blood or other potentially infectious materials to pass through or reach the employees' clothing, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time that the protective equipment will be used.

Personal protective equipment includes but is not limited to: gloves, surgical gowns, laboratory coats and jackets, face shields, masks, protective eyewear

with solid side shields and shoe covers.

The PRINCIPAL INVESTIGATOR/AREA SUPERVISOR will ensure that personal protective equipment is provided and worn by employees as needed and that training in the proper wearing and use of such equipment is provided.

The PRINCIPAL INVESTIGATOR/AREA SUPERVISOR will list how personal protective equipment will be provided, i.e., its location and/or who has responsibility for its distribution. (Complete Appendix C, # 6a.)

All personal protective equipment will be cleaned, laundered, and disposed of by the employer at no cost to employees. **Soiled personal protective equipment must not be taken home to launder.** The employer will make all repairs and replacements at no cost to employees.

All garments that are penetrated by blood shall be removed immediately or as soon as feasible. All personal protective equipment will be removed prior to leaving the work area.

The PRINCIPAL INVESTIGATOR/AREA SUPERVISOR shall list where employees are expected to place the personal protective equipment upon leaving the work area. (Complete Appendix C, # 6b.)

- a) **Gloves:** Gloves shall be worn where it is reasonably anticipated that employees may have hand contact with blood, other potentially infectious materials, non-intact skin and mucous membranes, and when handling or touching contaminated items or surfaces. Routine gloving is required for all phlebotomies. EHRS recommends the use of nitrile, powder-free latex or latex-free products to help prevent latex allergy. More information on [latex allergy](http://www.ehrs.upenn.edu/programs/occupat/latex_allergy.html) can be found at the EHRS website (http://www.ehrs.upenn.edu/programs/occupat/latex_allergy.html).

The PRINCIPAL INVESTIGATOR/AREA SUPERVISOR will list the procedures in their areas that require the use of gloves. (Complete Appendix C, # 7a.)

Disposable gloves are not to be washed or decontaminated for re-use and are to be replaced as soon as practical when they become contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised.

Utility gloves may be decontaminated for re-use provided that the integrity of the glove is not compromised. Utility gloves will be discarded if they are cracked, peeling, torn, punctured, or exhibit other signs of deterioration or when their ability to function as a barrier is compromised.

- b) **Masks:** Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin length face shields, are required to be worn whenever splashes, spray, splatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can reasonably be anticipated.

If work requires the use of a respirator, employees must participate in the [University's respiratory protection program](http://www.ehrs.upenn.edu/programs/occupat/upennresp.html) (<http://www.ehrs.upenn.edu/programs/occupat/upennresp.html>).

Personnel must have prior medical clearance to wear a respirator and must consult with EHRS on the selection and use of respiratory protective equipment.

The PRINCIPAL INVESTIGATOR/AREA SUPERVISOR will list situations in their areas that require such protection. (Complete Appendix C, # 7b.)

- c) **Protective clothing:** Appropriate protective clothing shall be used, such as lab coats, gowns, aprons, clinic jackets, or similar outer garments. Disposable water-repellent overgowns shall be worn when contamination with blood or other potentially infectious materials is anticipated.

The PRINCIPAL INVESTIGATOR/AREA SUPERVISOR will list situations that require the use of such protective clothing. (Complete Appendix C, # 7c.)

- vii. **Cleaning:** The facility will be cleaned according to PENN Facilities Services schedule. **The PRINCIPAL INVESTIGATOR/ AREA SUPERVISOR shall ensure that the laboratory is maintained in a clean and sanitary fashion.**
- viii. **Decontamination: Establishing decontamination procedures is the responsibility of the PRINCIPAL INVESTIGATOR/AREA SUPERVISOR.** A 1:10 (for a high organic load e.g. blood spill) or 1:100 dilution (for surface decontamination) of household bleach made fresh daily is recommended for use in most circumstances. For further assistance in selecting an appropriate disinfectant, contact EHRS (ehrs@ehrs.upenn.edu).

All contaminated work surfaces will be decontaminated:

- after completion of procedures.
- immediately or as soon as feasible after any spill of blood or other potentially infectious materials.
- at the end of the workday if the surface may have become contaminated since the last cleaning.

Contaminated plastic backed absorbent pads shall be removed immediately or as soon as feasible after any spill of blood or other potentially infectious materials as well as at the end of the workday.

All bins, pails, cans, and similar receptacles shall be inspected and decontaminated according to a schedule to be determined by the facility manager of each school.

Any broken glassware which may be contaminated must not be picked up directly with bare or gloved hands. It must be removed by mechanical means such as tongs and/or dustpans and broom and placed in an appropriate infectious waste sharps container.

Lab personnel must be prepared to respond to spills of potentially infectious materials in their areas. [Biohazardous spill response procedures](http://www.ehrs.upenn.edu/emergency/bio.html) are available at the EHRS website (<http://www.ehrs.upenn.edu/emergency/bio.html>).

The PRINCIPAL INVESTIGATOR/AREA SUPERVISOR will describe the procedure to be used for decontamination and spill cleanup. (Complete Appendix C, #8.)

- ix. **Infectious Waste:** Infectious waste shall be placed in appropriate infectious waste containers located in laboratories or clinical areas. All infectious waste from laboratories must be autoclaved prior to disposal. Contact the facility manager or EHRS for waste disposal information specific to your area. For more [information on infectious waste](http://www.ehrs.upenn.edu/resources/waste/bio/default.html), consult the EHRS web site (<http://www.ehrs.upenn.edu/resources/waste/bio/default.html>).
- x. **Laundry Procedures:** Apparel contaminated with blood or other potentially infectious materials will be handled as little as possible. Such apparel will be

decontaminated, preferably by autoclaving, before it is sent to a laundry for cleaning. Such apparel will not be sorted or rinsed in the area of use.

All employees who handle contaminated apparel will utilize personal protective equipment to prevent contact w/ blood or other potentially infectious materials.

xi. Labeling and Signs:

- a) Labels:** Biohazard warning labels shall be attached to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious materials, lab equipment in which biohazards are stored or used (e.g. incubators, centrifuges, etc.), and other containers used to transport or ship blood or other potentially infectious materials.

Labels shall:

- 1) include the universal biohazard symbol.
- 2) be fluorescent orange or orange-red or predominantly so with lettering or symbols in a contrasting color.
- 3) red bags or containers may be substituted for labels.



- b) Signs:** Biohazard warning signs shall be posted at the entrance to HIV/HBV research laboratories and other work areas in which biohazards are used. Contact EHRS to [request a room sign](#) (<http://www.ehrs.upenn.edu/programs/labsafety/chp/appendixi.html>).

c. Medical Surveillance

In accordance with the [Health Insurance Portability and Accountability Act](#) or HIPAA (<http://www.hhs.gov/ocr/hipaa/>), effective April 14, 2003, all patient-related medical information will be kept confidential.

- 1) Hepatitis B Vaccine:** The PRINCIPAL INVESTIGATOR/AREA SUPERVISOR will ensure that all employees who have been identified as having exposure to blood or other potentially infectious materials are offered the Hepatitis B vaccine, at no cost to the employee. The vaccine will be offered within 10 working days of their initial assignment to work involving the potential for occupational exposure to blood or other potentially infectious materials.

The vaccine will be administered to the employee by or under a licensed physician or under supervision of another licensed health care professional. It will be made available to the employee during normal work hours at a reasonable time. Occupational Medicine administers the vaccine at:

**Occupational Medicine
Penn Tower 4th floor
300 South 33rd Street
Philadelphia, PA 19104-4283
215-662-2354**

Employees who decline the Hepatitis B vaccine will be asked to sign a Declination waiver that uses the following wording:

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

A copy of the [Hepatitis B Declination waiver](http://www.ehrs.upenn.edu/programs/bio/declination.html) can be found on the EHRS web site (<http://www.ehrs.upenn.edu/programs/bio/declination.html>) The vaccine will be provided at no cost to employees who initially decline the vaccine but later wish to receive it. (changed order of sentences)

- 2) **Post-Exposure Evaluation and Follow-Up:** When an employee incurs an exposure, it should be reported to the *PRINCIPAL INVESTIGATOR/ AREA SUPERVISOR* and EHRS at 215-898-4453.

All employees who incur an exposure will be offered post-exposure evaluation and follow-up in accordance with the OSHA Bloodborne Pathogens Standard. When an employee incurs an exposure, he/she should report to:

Occupational Medicine
Penn Tower 4th floor
300 South 33rd Street
Philadelphia, PA 19104-4283
Phone: 215-662-2354
Monday through Friday 8:00 a.m. – 3:30 p.m.

All other times report to:

Emergency Department
Silverstein Pavilion, ground floor
HUP/UPMC

The evaluation and follow-up will include the following under the direction of the director of Occupational Medicine:

- Documentation of the route of exposure and the circumstances related to the incident.
 - If possible, the identification of the source individual and, if possible, the status of the source individual. The blood of the source individual will be tested (**after consent is obtained by the *PRINCIPAL INVESTIGATOR/ AREA SUPERVISOR***) for HIV/HBV infectivity.
 - Results of testing of the source individual will be made available to the exposed employee along with information about the applicable laws and regulations concerning disclosure of the identity and infectivity of the source individual.
 - The employee will be offered the option of having blood collected for testing of his/her HIV/HBV serological status. The blood sampling will be preserved for at least 90 days to allow the employee to decide if the blood should be tested for HIV serological status. However, if the employee decides prior to that time that testing will be conducted then the blood sample will be discarded after the results are obtained.
 - The employee will be offered post exposure prophylaxis in accordance with the current recommendations of the U.S. Public Health Service (USPHS). For a copy of these recommendations, call EHRS at 215-898-4453.
 - The employee will be given appropriate counseling concerning precautions to take during the period after the exposure incident. The employee will also be given information on potential signs and symptoms of illness and told to report these to Occupational Medicine, should they occur.
 - Medical records will be obtained and kept in accordance with all applicable regulations.
- 3) **Interaction with Health Care Professional:** The health care provider shall provide EHRS with a written opinion within 15 days after the exposed employee has been evaluated. Written opinions will be obtained in the following instances:
- i) when the employee is sent to obtain the Hepatitis B vaccine.
 - ii) whenever the employee is sent to a health care professional following an exposure incident.

Health care professionals shall be instructed to limit their opinions to:

- i) whether the Hepatitis B vaccine is indicated and if the employee has received the vaccine,
- ii) that the employee has been informed of the results of the evaluation, and
- iii) that the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials.

The written opinion to the employer must not reference any personal medical information.

d. Evaluative Measures

EHRIS shall solicit input from employees who are exposed due to a needlestick or percutaneous injury. In accordance with HIPAA, all patient-related medical information will be kept confidential. As part of the University program to develop safer alternative work practices associated with exposure, injury evaluation results and recommendations will be made available in the [Exposure Control Plan, Appendix F](http://www.ehrs.upenn.edu/programs/bio/ecp/appendixf.html) (<http://www.ehrs.upenn.edu/programs/bio/ecp/appendixf.html>).

e. Information and Training

- 1) **Training:** Training for all employees potentially at-risk will be conducted *prior* to initial assignment to tasks where occupational exposure to human source materials or other potential infectious materials may occur. Training will be conducted by EHRIS. Interactive and web-based training modules, videotapes, slides and written materials are used. Additional [information about training](http://www.ehrs.upenn.edu/training/index.html) is available at the EHRIS web site (<http://www.ehrs.upenn.edu/training/index.html>).

Training for employees will include the following:

- Details of the OSHA standard, "Occupational Exposure to Bloodborne Pathogens".
- Epidemiology, symptomatology and mode of transmission of bloodborne diseases.
- This Exposure Control Plan, i.e., points of the plan, lines of responsibility, how the plan will be implemented, etc.
- Procedures that might cause exposure to blood or other potentially infectious materials.
- Methods used to control exposure to blood or other potentially infectious materials.
- Personal protective equipment available and who should be contacted concerning its provision, replacement and laundering.
- Post-exposure evaluation and follow-up.
- Signs and labels.
- Hepatitis B vaccine program.

Employees will receive annual refresher training, which will be conducted within one year of the employee's previous training.

ADDITIONAL TRAINING REQUIRED FOR EMPLOYEES WHO WORK IN HIV/HBV RESEARCH LABORATORIES WILL BE PROVIDED BY *PRINCIPAL INVESTIGATORS/AREA SUPERVISORS* IN CONSULTATION WITH EHRIS.

The outline for training material is located at the:

EHRIS
3160 Chestnut Street, Suite 400
Philadelphia, PA 19104-6287
215-898-4453

A copy of the OSHA standard "[Occupational Exposure to Bloodborne Pathogens](http://www.osha-slc.gov/needlesticks/needlesticks-regtxtrev.html)" may be obtained from the OSHA web site (<http://www.osha-slc.gov/needlesticks/needlesticks-regtxtrev.html>) or by calling EHRIS at 215-898-4453.

2) Record keeping

All training records required by the OSHA standard will be maintained by the:

Office of Environmental Health & Radiation Safety (EHRS)
3160 Chestnut Street, Suite 400
Philadelphia, PA 19104-6287

Medical records will be maintained by:

Occupational Medicine,
Penn Tower, 4th Floor
300 South 33rd Street
Philadelphia, PA 19104-4283
Phone: 215-662-2354

3) Dates

All provisions required by the Occupational Exposure to Bloodborne Pathogens Standard, rev. 2001, were implemented by July 18, 2001.

f. HIV/HBV Research Laboratories

The *PRINCIPAL INVESTIGATOR/AREA SUPERVISOR* shall consult with EHRS for a description of applicable criteria and additional training required for employees who work in HIV/HBV research laboratories.

Appendix A

Job classifications in which all employees may be expected to incur occupational exposure to blood or other potentially infectious materials:

ASST COACH A	HEAD COACH W LACROSSE
ASST COACH FOOTBALL	HEAD COACH W TRACK & FIELD
ASST COACH M & W SWIMMING	HEAD COACH W VOLLEYBALL
ASST COACH M BASKETBALL	HEAD COACH W BASKETBALL
ASST COACH M TRACK & FIELD	HEAD COACH WOMEN'S CREW
ASST COACH MEN'S CREW	HEAD COACH WOMEN'S SOCCER
ASST COACH MEN'S LACROSSE	HEAD COACH WOMEN'S SQUASH
ASST COACH MEN'S SWIMMING	HEAD COACH WOMEN'S TENNIS
ASST COACH STRNGTH/FITNS	HEAD COACH WRESTLING
ASST COACH W BASKETBALL	HEALTH PHYSICS TECH
ASST COACH W GOLF	HEALTH PHYSICS TECH SR
ASST COACH W TRACK & FIELD	HEALTH PHYSICS TECH TRAIN
ASST COACH W VOLLEYBALL	INDUSTRIAL HYGIENIST
ASST COACH WOMEN LACROSSE	INDUSTRIAL HYGIENIST SR
ASST COACH WOMEN'S CREW	INSPECTOR SAFETY
ASST COACH WRESTLING	INST BIOSAFETY OFF
ASST COACH/ATHLETIC_ADMIN	INTERNAL MEDICAL
ASSC DIR EV HTH & RAD SAF	MAINTENANCE MECH
ASSOC DIR STUD HEALTH	MECH MAINTENANCE SR
ASSOC DIRECTOR IHGT	MED HEALTH PHYSICIST JR
ATHLETIC TRAINER	MED PHYS/DIR DOSMTRY SERV
CAPTAIN UNIV POLICE	MEDICAL HEALTH PHYS SR
CHIEF OF POLICE	MEDICAL HEALTH PHYSICIST
CLINICAL SPECIALIST	MEDICAL PHYSICIST
COORDNTR CLINICAL RESRCH	MEDICAL PHYSICIST SR
CPUP CLINICAL POSITION	MGR CAMPUS MAINTENANCE
CPUP CLINICAL POSITION E	MGR FIRE & OCCUPTNL SAFTY
DENTAL ASSISTANT A	MGR SPORTS MED/HD TR
DENTAL ASSISTANT B	NURSE A
DENTAL ASSISTANT C	NURSE ASSISTANT
DEPUTY CHIEF UNIV POLICE	NURSE B
DETECTIVE	NURSE PRACTITIONER
DETECTIVE SERGEANT	NURSE SUPERVISOR
DIR CLINICAL PRACTICE	NURSE, LICENSED PRACTICAL
DIR DENTAL CARE CENTER	OCCUPATIONAL THERAPIST
DIR ENVIR HLTH & RAD SAF	PARAMEDIC
DIR STUDENT HEALTH SERV	PHARMACIST
DIRECTOR CLINICAL TRIALS	PHARMACY ASSISTANT A
ENVRMTL HLTH & SFTY SPEC	PHARMACY ASSISTANT B
EMBALMER	PHYSICIANS ASSISTANT
HEAD COACH BASEBALL	SAFETY OFF BIOLOG SR
HEAD COACH FIELD HOCKEY	SAFETY OFFICER BIO
HEAD COACH FOOTBALL	SAFETY SPECIALIST
HEAD COACH M & W FENCING	SERGEANT UNIV POLICE
HEAD COACH M & W SWIMMING	STAFF DENTIST
HEAD COACH M BASKETBALL	STAFF PHYSICIAN
HEAD COACH M TRACK & FIELD	SUPERVISOR DENTAL
HEAD COACH MEN'S CREW	SUPV CLINICAL LAB (CERT)
HEAD COACH MEN'S FENCING	SUPV DETECTIVES
HEAD COACH MEN'S LACROSSE	TEACHER CHILDREN'S CTR
HEAD COACH MEN'S SOCCER	TECH AUTOPSY
HEAD COACH MEN'S SQUASH	TECH CLINICAL A
HEAD COACH MEN'S SWIMMING	TECH CLINICAL B
HEAD COACH MEN'S TENNIS	TECH DENTAL
HEAD COACH SOFTBALL	TECH HEALTH & SAFETY
HEAD COACH W GYMNASTICS	TECH HISTOLOGY

TECH HISTOLOGY SR
TECH MRI
TECH OPHTHALM C
TECH OPHTHALMIC A
TECH OPHTHALM B
TECH PSG SLEEP CENTER
TECH REGISTERED PSG
TECH SLEEP CENTER
TECH CYTOGENETICS
TECHNOLOGIST MEDICAL

TECHNOLOGIST NUCLEAR
TECHNOLOGIST PET
TECHNOLOGIST PET SR
TECHNOLOGIST RADIOLOG
TEMP LAB ASSIST
TEMP LAB TECH
TEMP MED AIDE
TEMP RESEARCH ASST
UNIV POLICE CORPORAL
UNIVERSITY POLICE

Appendix B

Job classifications in which some employees may have occupational exposure, regardless of frequency, especially those in the following Schools/Departments: Dental Medicine, Medicine, Biology, Bioengineering:

ADMIN ASST A, B	LAB ANIMAL ASSISTANT
AIRCONDNG REFRIG MECH	LAB SERVICES ASST A, B, C, D
APPRENTICE	MANAGER FACILITIES
ASSC DIR ATHLETICS SR	MANAGER ULAR
ASSISTANT MANAGER A, B, C	MED OFFICE ASST
ASSOC DIR FACILITIES	MGR ATHLETIC EQUIPMENT
ASSOC DIR LAB ANIM HUSB	MGR RES PROJECT A, B, C
ASSOC DIR RESIDENCE	MGR SPORTS MED/HD TR
ASSOC DIR UTILITIES & ENG	NURSE VET A
ASSOC DIRECTOR A, B, C, D, E	OFFC ADMNST ASST A, B
ASSOC VP/CAMPUS SVCS	OFFENSIVE COORD FOOTBALL
ASSOC VICE PROV/UNIV LIFE	OUTREACH WORKER
ASST COACH A, B, C	PART TIME PROFESSIONAL
ASST COACH/ATHLETIC ADMIN	PLUMBER
ASST FACILITIES MANAGER	PHYSICAL THERAPIST
ASST SUPV CUSTODIAL (NBC)	PLUMBER
ASST SUPV LARGE ANIMAL	RECEPTIONIST A, B
ASST VICE PROV RESEARCH	RECEPTIONIST CLINICAL
ATHLETIC CREW RIGGER	RECREATION ASSISTANT
ATTENDANT LARGE ANIMAL A, B, C	RECREATION THER/ACT DIR
AVP FACILITIES OPERATIONS	REGULAR PART TIME EMP
BLDG ADMINISTRATOR	RESEARCH ADMINISTRATOR SR
BLDG ADMINISTRATOR SENIOR	RESEARCH COORDINATOR
BLDG OPER MANAGER	RESEARCH COORDINATOR SR
CAREGIVER	RESEARCH INVESTIGATOR SR
CARETAKER	RESEARCH SPECIALIST A, B, C, D
CARPENTER	SECRETARY TECH MED
COORDINATOR A, B	SERVICE MECHANIC
COORDINATOR LABS	SERVICES ASSISTANT A, B, C, D
COORDNTR INSTRUCTION LABS	SPORTS MEDICINE TECH A
COORDNTR REC/ATHLETICS	SPORTS MEDICINE TECH B
CUSTODIAN	SPORTS MEDICINE TECH C
DEFENSIVE COORD FOOTBALL	SPORTS MEDICINE D
DIR ANIMAL CARE OPS	STAFF ASSISTANT A, B, C
DIR ANIMAL MODELS CORE	STAFF RESEARCHER A, B
DIR ANIMAL SERVICE IHGT	STAFF VET
DIR CHILDRENS CTR	STERILIZATION ATTEND SR
DIR DIV LAB ANIMAL MED	STERILIZATION ATTENDANT
DIR FACILITIES SERVICES	SUPERVISOR EXEMPT A, B
DIR FIRE & EMERGENCY SVCS	SUPERVISOR NON EXEMPT
DIR INST NEUROLOG SCI	SUPERVISOR SERVICES
DIR INSTITUTIONAL RESRCH	SUPERVISOR TECH
DIR INTERCOLG ATHLETICS	SUPV ATTNDNT LG ANIMAL
DIR RECREATION	SUPV CAMPUS MAINTENANCE
DIR SPECIAL SERVICES	SUPV LAB ANIMAL
ELECTRICIAN	SUPV NURSING VET
ELECTRICAL OPERATOR	SUPV VET ANESTH
ENGR PRESSURE CHAMBER	TECH ASST LAB ANIMAL
EXEC DIR PENN CANCER CNTR	TECH INSTRUMENTATION
FACILITIES MANAGER A	TECH LAB ANIMAL
FACILITIES PLANNER	TECH MECHANICAL
FARM SUPERVISOR	TECH PRESSURE CHAMBER
FARM WORKER	TECH PSYCHOLOGY
FILTERPERSON	TECH RESEARCH LAB A, B, C
HELPER	TECH TRAINING SPEC
INSTRUMNT STERIL ATTN A, B	TECH TRAINING SPEC SR

TECH ULTRASOUND
TECH ULTRASOUND SR
TECH VET A, B, C, D
TECH VET ANESTH
TECH VET ANESTH SR
TECH VET ANESTH TRN
TECH VET IMAGING A, B, C
TECH VET OR
TECH VET OR SR
TECH VET SR
TECH VET TRAINEE
TECH X-RAY
TECH X-RAY SR
TECHNLGIST LAB ANIMAL
VET NURSE ASST A, B
VET NURSE B
VET TECH A
VET TECH ANESTHESIA A
VET TECH ANESTHESIA B
VET TECH ANESTHESIA C
VET TECH ANESTHESIA D
VET TECH EMERG SVCS A
VET TECH EMERG SVCS B
VET TECH EMERG SVCS C

VET TECH EMERG SVCS D
VET TECH ICU A
VET TECH ICU B
VET TECH ICU C
VET TECH ICU D
VET TECH IMAGING A
VET TECH IMAGING B
VET TECH IMAGING C
VET TECH IMAGING D
VET TECH OR A
VET TECH OR B
VET TECH OR C
VET TECH OR D
VET TECH TRAINEE
VET TECH WARD A
VET TECH WARD B
VET TECH WARD C
VET TECH WARD D
VET TECH WARD/ICU A
VET TECH WARD/ICU B
VET TECH WARD/ICU C
VET TECH WARD/ICU D
VETERINARY HEAD NURSE

Appendix C

To be completed by the *PRINCIPAL INVESTIGATOR / AREA SUPERVISOR*:

1. List additional job classifications not listed in Appendices A or B in which employees may have occupational exposure to blood or bloodborne pathogens. This assessment will be made without regard for the use of personal protective equipment. (See p. 4 of the Exposure Control Plan.)

2. For those job classifications in which some employees may have occupational exposure to blood or bloodborne pathogens, list those associated tasks or procedures that would cause employees to have potential occupational exposure. (See p. 4 of the Exposure Control Plan.)

3. Identify methods that will be employed to minimize splashing, spraying, splattering and generation of blood or other potentially infectious materials. (See p. 6 of the Exposure Control Plan.)

4. Specify which specimens, if any, could puncture a primary container, which containers to use as secondary containers and where secondary containers are located. (See pp. 6-7 of the Exposure Control Plan.)

5. List any equipment which cannot be decontaminated prior to servicing or shipping. (See p. 7 of the Exposure Control Plan.)

6. a. List how personal protective clothing will be provided, i.e., its location and/or who has responsibility for its distribution. (See p. 7 of the Exposure Control Plan.)

6. b. List where employees are expected to place personal protective equipment upon leaving the work area. (See p. 8 of the Exposure Control Plan.)

7. a. List procedures that require the use of gloves. (See p. 8 of the Exposure Control Plan.)

7. **b.** List situations that require the use of facial protection (masks, face shields, protective eyewear. (See p. 8 of the Exposure Control Plan.)

7. **c.** List situations that require the use of protective clothing (lab coats, gowns, aprons, clinic jackets, etc.). (See p. 8 of the Exposure Control Plan.)

8. Describe the procedure to be used for decontamination and spill cleanup. (See pp. 8-9 of the Exposure Control Plan.)

Appendix D

University of Pennsylvania Tuberculosis (TB) Exposure Control Plan

I. Introduction:

In 1994, CDC published the *Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Facilities, 1994*. These guidelines were issued in response to (1) a resurgence of tuberculosis (TB) disease that occurred in the United States in the mid-1980's and early 1990's, (2) the documentation of several high-profile health-care-associated (previously termed "nosocomial") outbreaks related to an increase in the prevalence of TB disease and human immunodeficiency virus (HIV) coinfection, (3) lapses in infection-control practices, (4) delays in the diagnosis and treatment of persons with infectious TB disease, and (5) the appearance and transmission of multidrug-resistant (MDR) TB strains.

The TB infection-control measures recommended in the CDC guidelines were implemented in health-care facilities in the United States and have resulted in a decrease in the number of TB outbreaks in health care settings and a reduction in health-care-associated transmission of *Mycobacterium tuberculosis* to patients and health-care workers (HCWs).

In 2005, CDC released new guidelines, *Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-care Settings, 2005*. These guidelines have been expanded to address a broader concept; health-care-associated settings go beyond the previously defined facilities. The term "health-care setting" includes many types, such as inpatient settings, outpatient setting, TB clinics, settings in correctional facilities in which health care is delivered, settings in which home-based health-care and emergency medical services are provided, and laboratories handling clinical specimens that might contain *M. tuberculosis*.

The national strategic plan for TB elimination is <1 case per 1,000,000 population by 2010. Despite the general decline in TB rates in recent years, a marked geographic variation in TB case rates persists, which means that HCWs in different areas face different risks. In the United States, the 2004 rate of 4.9 per 100,000 population remained higher than the 2000 goal of 3.5.

II. Pathogenesis, Epidemiology, and Transmission of *M. tuberculosis*

M. tuberculosis is carried in airborne particles called droplet nuclei that can be generated when persons who have pulmonary or laryngeal TB disease cough, sneeze, shout, or sing. The particles are approximately 1 – 5 microns; normal air currents can keep them airborne for prolonged periods and spread them throughout a room or building. *M. tuberculosis* is usually transmitted only through air, not by surface contact. After the droplet nuclei are in the alveoli, local infection might be established, followed by dissemination to draining lymphatic and hematogenous spread throughout the body. Infection occurs when a susceptible person inhales droplet nuclei containing *M. tuberculosis*, and the droplet nuclei traverse the mouth or nasal passages, upper respiratory tract, and bronchi to reach the alveoli.

Usually within 2 – 12 weeks after initial infection with *M. tuberculosis*, the immune response limits additional multiplication of the tubercle bacilli, and immunologic test results for *M. tuberculosis* infection become positive. However, certain bacilli remain in the body and are viable for multiple years. This condition is referred to as latent tuberculosis infection (LTBI). Persons with LTBI are asymptomatic and are not infectious.

In the United States, LTBI has been diagnosed traditionally based on a PPD-based TST result after TB disease has been excluded. In vitro cytokine-based immunoassays for the detection of *M. tuberculosis* infection have been the focus of intense research and development. The QuantiFERON-TB test (QFT), is a blood assay for *M. tuberculosis* (BAMT). These tests measure cell-mediated immune responses to peptides from two *M. tuberculosis* proteins that are not present in any Bacille Calmette-Guerin (BCG) vaccine strain and that are absent from the majority of nontuberculosis mycobacteria (NTM). Cytokine-based immunoassays are under development and might be useful in the diagnosis of *M. tuberculosis* infections.

Typically, approximately 5% to 10% of persons who become infected with *M. tuberculosis* and who are not treated for LTBI will develop TB disease during their lifetimes. The risk for progression of LTBI to TB disease is highest during the first several years after infection.

III. Who should be in a TB surveillance program?

Persons who work in healthcare settings where they may have the potential to be exposed to *M. tuberculosis* should be in a surveillance program. These persons can be but not limited to: physicians, dentists, nurses, aides, dental workers, technicians, workers in laboratories and morgues, emergency medical personnel, students, part-time personnel, temporary staff not employed by the University, and person not directly involved in patient care but who are potentially at risk for occupational exposure to *M. tuberculosis*, as volunteer workers, dietary, housekeeping, maintenance, clerical and janitorial staff.

IV. Risks for health-care-associated transmission of *M. tuberculosis* (TB)

Transmission of *M. tuberculosis* is a risk in health-care settings. The magnitude of the risk varies by setting, occupational group, the prevalence of TB in the community, the patient population, and effectiveness of TB infection-control measures. Health-care-associated transmission of *M. tuberculosis* has been linked to close contact with persons with TB disease during aerosol-generating or aerosol-producing procedures, including bronchoscopy, endotracheal intubation, suctioning other respiratory procedures, open abscess irrigation, autopsy, sputum induction, and aerosol treatments that induce coughing.

The risk for transmission of *M. tuberculosis* varies also for those working in a laboratory setting where manipulation of patient cultures and the mycobacterium itself is taking place and those working with non-human primates.

V. Fundamentals of Infection Control

Transmission of *Mycobacterium tuberculosis* is most likely to occur from patients with unrecognized TB, patients that have not been properly handled with appropriate airborne precautions, and those patients that have not been on effective anti-tuberculosis therapy.

All health care settings need a TB infection-control program designed to ensure prompt detection, airborne precautions, and treatment of persons who have suspected or confirmed TB disease. Such a program is based on a three-level hierarchy of controls; administrative controls, environmental controls, and respiratory-protection controls.

A. Administrative Controls

The first and most important level of TB controls is the use of administrative measures to reduce the risk for exposure to persons who might have TB disease. Administrative controls consist of the following:

- Assigning responsibility for TB infection control in the setting
- Conduct a TB risk assessment in the setting
- Develop and institute a written TB infection-control plan to ensure prompt detection; airborne precautions, and treatment of persons who have suspected or conformed TB disease
- Training and education HCWs regarding TB, with specific focus on prevention, transmission and symptoms
- Screening and evaluating HCWs who are at risk for TB disease or who might be exposed to *M. tuberculosis*
- Using appropriate signage advising respiratory hygiene and cough etiquette
- Coordinating efforts with the local or state health department

B. Engineering Controls

Engineering controls are used to prevent the spread and reduce the concentration of infectious droplet nuclei in ambient air.

Primary environmental controls consist of controlling the source of infection by using local exhaust ventilation and diluting and removing contaminated air by using general ventilation.

Treatment rooms must have negative air pressure to adjacent areas and a minimum of six air changes per hour in existing facilities. New facilities must have at least 12 air changes per hour in treatment areas. Negative pressure inside the treatment room permits air to be drawn into the room and prevents the escape to adjacent areas. The room air being exhausted must not be recirculated. If the air needs to be recirculated, it must be subjected to HEPA filtration.

C. Respiratory-protection controls

The first 2 levels minimize the number of areas in which exposure to *M. tuberculosis* might occur and therefore, minimize the number of persons exposed. Because persons entering these areas might be still exposed to *M. tuberculosis*, the third level of the hierarchy is the use of respiratory protective equipment in situations that pose a high risk for exposure. The use of respiratory protection can further reduce risk for exposure of HCWs to infectious droplet nuclei when environmental controls may not provide adequate protection.

Appropriate respiratory protection must be provided without cost to staff that are at-risk. Before using a respirator, personnel must:

1. Report to HUP Occupational Medicine for medical evaluation.
2. Contact EHRS (215-898-4453) for training in respirator selection, fit testing and use.

VI. Laboratories

Procedures involving the manipulation of specimens or cultures containing *M. tuberculosis* introduce substantial risks that must be addressed in an effective TB infection-control program. Personnel who work with mycobacteria specimens should be thoroughly trained in methods that minimize the production of aerosols and undergo periodic competency testing to include direct observation of their work practices. Risks for transmission of *M. tuberculosis* in laboratories include aerosol formation during any specimen or isolate manipulation and percutaneous inoculation from accidental exposures. Tubercle bacilli may be present in sputum, gastric lavage fluids, CSF, urine and tissue.

Factors to consider when developing a risk-based infection control plan for the laboratory:

- The incidence of TB disease (including drug-resistant TB) in the community and in patients served by settings that submit specimens to the laboratory
- Design of the laboratory
- The level of TB diagnostic service offered
- The number of specimens processed
- Whether or not aerosol generating or aerosol-producing procedures are performed and the frequency at which they are performed.

Biosafety level 2 (BSL-2) practices and procedures, containment equipment and facilities are required for nonaerosol producing manipulation of clinical specimens. Examples are preparing direct smear for acid-fast staining when done in conjunction with training and periodic checking of competency. All specimens suspected of containing *M. tuberculosis* should be handled in a Class I or Class II biological safety cabinet (BSC). Conduct all aerosol-generating activities in a Class I or Class II BSC. These procedures include inoculating

culture media, setting up biochemical and antimicrobial susceptibility test, opening centrifuge cups and performing sonication procedures.

Biosafety level-3 (BSL-3) practices and procedures, containment equipment, and facilities are recommended for the propagation and manipulation of cultures of *M. tuberculosis* complex (including *Mycobacterium bovis*) and for animal studies in which primates that are experimentally or naturally infected with *M. tuberculosis* or *M. bovis* are used. Animal studies in which guinea pigs or mice are used can be conducted at animal BSL-2. BSL-3 practices, containment and facilities are required for laboratory activities in the propagation and manipulation of cultures of any of the subspecies of the *M. tuberculosis* complex and for animal studies using experimentally or naturally infected NHP. Animal studies using guinea pigs or mice can be conducted at ABSL-2.

For all laboratory procedures, appropriate PPE shall be worn. Gloves shall be disposed of when work is completed, the gloves are noticeable contaminated or the integrity of the glove is compromised. Respiratory protection and the implementation of specific procedures and use of specialized equipment are needed to prevent and contain aerosols. The minimum level of respiratory protection is an N95 filtering facepiece respirator. Laboratory workers must also receive training on respiratory use, care and fit testing from the Office of Environmental Health and Radiation Safety and medical clearance from Occupational Medicine.

All use of *M. tuberculosis* or *M. bovis* and animal protocols using *M. tuberculosis* or *M. bovis* must be reviewed by the Institutional Biosafety Committee (IBC). Biosafety levels and animal biosafety levels will be determined by the IBC.

VII. What to do in the event of an exposure

If you believe you have been exposed to *M. tuberculosis* in the course of your duties at the University, you should discuss this with your supervisor for possible referral to Occupational Medicine for TB screening.

VIII. Screening of employees for TB

Every employee who is at risk for occupational exposure to TB must be screened on an annual basis. Persons working in high exposure areas or occupations should be screened twice annually.

The tuberculin skin testing (TST) is administered by Occupational Medicine. A positive TST reaction will result in further evaluation if necessary which may include a chest X-ray and the QuantiFERON-TB test (QFT blood assay test for TB- BAMT).

IX. References:

1. *Biosafety in Microbiological and Biomedical Laboratories*, 5th edition; Centers for Disease Control and Prevention and the National Institutes of Health, December 2009.
2. Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005; Morbidity and Mortality Weekly Report, December 30, 2005/Vol.54/No.RR-17.

Appendix E

**University of Pennsylvania
Environmental Health and Radiation Safety**

Post Exposure Evaluation Form
Needlestick and/or Other Sharp Object Injuries

Instructions: Complete this form to assist the University develop safer alternative work practices associated with needlesticks or other sharps injuries. Keep a copy of this form for your records. Return the completed form to EHRS, Suite 400, 3160 Chestnut Street/ 6287 or by FAX: 215-898-0140.

Employee Information:

Name: _____ PENN ID #: _____
Position/Title: _____ School/Department: _____
Mailing Address: _____ Mail Code: _____
Telephone: _____ FAX: _____
E-mail: _____ Emergency Telephone: _____
Principal Investigator: _____ Telephone: _____

Injury Information:

Date and time of injury: _____ Body Part Injured (specific): _____
Location where injury occurred (specific laboratory room, clinical area, etc.): _____
What type of Personal Protective Equipment (PPE) were you wearing at the time of the exposure incident?
 lab coat gloves safety glasses other, specify: _____

Procedure being performed at time of injury: _____
Describe how the incident occurred: _____

Device Information:

Identify Sharp Involved (if known): _____
Type: _____ Brand: _____ Model: _____
Did the sharps have engineered sharps injury protection? Yes No Don't know
Was the protective mechanism activated? Yes No Don't know
When did the exposure incident occur?
 Before activation During activation After Activation

Do you have an opinion that any other engineering control, administrative or work practice could have prevented the injury? Yes No Don't know
Describe: _____

Appendix F

Evaluative Recommendations

EHRH collects information from employees who have had an exposure to potentially infectious materials. EHRH has evaluated the information and presents the following recommendations:

Handling Trash Bags – EHRH investigated several incidents of housekeeper injuries during trash bag removal from University spaces due to improperly discarded sharps. University policy mandates the disposal of sharp items in a rigid sharps container to prevent any accidental injury. Complete [guidelines for the management of all sharps](http://www.ehrs.upenn.edu/resources/waste/bio/usedsharps.html) are available at the EHRH website (<http://www.ehrs.upenn.edu/resources/waste/bio/usedsharps.html>).

When handling trash bags, it is recommended that housekeepers take precautions to prevent injury should sharps have been discarded improperly. Housekeepers should not compress trash bags nor remove trash bags if they notice improperly discarded sharps in the trash. The trash should be left in the area and the area housekeeping supervisor informed of the mismanaged materials. The housekeeping supervisor should contact EHRH and a biosafety officer will discuss the matter with the laboratory supervisor.

Removing Scalpel Blades - Improper handling of scalpel blades creates a safety hazard to the user. Use mechanical means (forceps, pliers, etc.) to remove a scalpel blade from the instrument handle whenever possible. Should mechanical means be unavailable, disinfect the instrument before attempting to remove the blade. Disposable scalpels with engineered sharps injury protection are strongly recommended.

Handling of Butterfly Needles - Several injuries occurred while handling butterfly needles in both the clinical and research settings. Problems arise when disposing of these items in sharps containers, due to additional tubing and adaptor parts associated with this device. Use special care when placing butterfly needles in sharps containers. If a sharps container is used primarily for butterfly needles, choose a sharps container with a wide opening to help resolve the problem. Disposable butterfly needles with engineered sharps injury protection are highly recommended.

Needlestick Injuries While Handling Animals - Several percutaneous injuries occurred as result of unexpected erratic movements by animal subjects. When handling needles and research animals, be sure the animal is properly restrained and/or tranquilized. Whenever possible, use syringes with engineered sharps injury protection.

Familiarity With New Products - Everyday new products enter the marketplace. Depending on factors such as price, convenience, safety-engineering and the natural progress of technology, they are adopted by individuals who may be unaware of the techniques needed to handle these devices properly. Splashes to mucous membranes and percutaneous injuries have occurred because of this unfamiliarity with a newly introduced device. EHRH highly recommends that individuals become familiar with newly introduced products before using them in situations involving human source material, biohazardous materials, and other hazardous substances. Practicing with a non-hazardous substitution helps hone one's technique and raises awareness of the limitations of the item.

Appendix G

University of Pennsylvania's Program for the Evaluation of Devices with Engineered Sharps Injury Protection

Occupational Safety and Health Administration OSHA announced changes to the [Bloodborne Pathogens Standard 29 CFR Part 1910.1030](http://www.osha-slc.gov/needlesticks/needlesticks-regtxtrev.html), (http://www.osha-slc.gov/needlesticks/needlesticks-regtxtrev.html) effective April 18, 2001. The [Needlestick Safety and Prevention Act](http://www.med.virginia.edu/epinet/hr5178rv.html) (http://www.med.virginia.edu/epinet/hr5178rv.html), effective April 18, 2001 (http://www.med.virginia.edu/epinet/hr5178rv.html), mandated these changes, which require employers to 1) select safer needle devices as they become available and 2) involve employees in identifying and choosing the devices to help reduce needlestick injuries among healthcare workers and others who handle medical sharps.

Since the revision, EHRS has been recruiting participants to evaluate devices with engineered sharps injury protection, which are defined as a non-needle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident. Volunteers have substituted devices with engineered sharps injury protection for regular sharps in an effort to evaluate the effectiveness of these devices. The outcome of these evaluations will be made available to University employees in the University's Exposure Control Plan.

Many University of Pennsylvania personnel covered by the Bloodborne Pathogens Standard work in a research setting. EHRS has chosen the following safety engineered sharps devices to evaluate at this time because they are most commonly used and have documented associations with injuries in the research setting.

To review the results of non-managerial employee evaluations of safety-engineered sharps devices, you must verify your affiliation with the University of Pennsylvania* with a University email address. Email EHRS at biohazregdoc@ehrs.upenn.edu for copies of the results below.

Results of the evaluation of **safety-engineered scalpels**:

- Futura™ LARK® Safety Scalpel
- BD Bard-Parker Protected Disposable Scalpel™
- Personna Safety Scalpel®
- EHRS recommendations

Results of the evaluation of **safety-engineered butterfly needles**:

- BD Vacutainer® Safety-Lok™ Blood Collection Set
- Kendall Monoject Angel Wing™ Blood Collection Set
- VACU-8 Blood Collection System
- EHRS recommendations

Evaluation of **safety-engineered syringes**:

EHRS is currently searching for volunteers. Interested? Email biohazregdoc@ehrs.upenn.edu or go to the EHRS website (<http://www.ehrs.upenn.edu/programs/bio/sharps.html>).

* **DISCLAIMER**

The Office of Environmental Health and Radiation Safety (EHRS), on behalf of the University of Pennsylvania and its Health System, conducted these product evaluations as part of its compliance with the Needlestick Safety and Prevention Act and the related Bloodborne Pathogens Standards issued by OSHA. EHRS did not receive any consideration or compensation from any product manufacturer or distributor whose product(s) were evaluated. The recommendations and opinions expressed on these pages are the result of the information gathered from employees, and do not reflect any individual employee's recommendation or opinion, or a recommendation or opinion for any purpose other than compliance with the Needlestick Safety and Prevention Act and the related OSHA regulations.