

# BIOLOGICAL SAFETY POLICY

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## 1.0 PURPOSE and APPLICABILITY

### 1.1

This policy is designed to ensure employees, students, and visitors follow safe work practices when working with or near biologically hazardous materials (infectious agents, biohazards or recombinant DNA).

### 1.2

This policy applies to University employees, students, and visitors who engage in any University-sponsored activity either on the Philadelphia campus, at New Bolton Center or the Morris Arboretum.

## 2.0 DEFINITIONS and SCOPE

### 2.1

"Biosafety", or biological safety, is a concept that promotes safe laboratory practices, procedures, and proper use of containment equipment and facilities by laboratory workers in the biomedical environment to prevent occupationally-acquired infections or release of organisms to the environment. Biosafety is the responsibility of all persons who manipulate pathogenic microorganisms and recombinant DNA molecules.

### 2.2

"Biohazards" are infectious agents or biologically derived infectious materials that present a risk or potential risk to the health of humans or animals, either directly through infection or indirectly through damage to the environment. Infectious agents have the ability to replicate and give rise to the potential of large populations in nature when small numbers are released from a controlled situation.

### 2.3

"Infectious waste" or "biohazardous waste" is defined by the Pennsylvania Department of Environmental Protection and includes cultures and stocks of infectious agents and associated biologicals, human pathological wastes, human blood, blood products and body fluids, contaminated animal wastes and carcasses, human and animal isolation wastes and contaminated used sharps (sharps that have been in contact with infectious agents or that have been used in

## **3.0 ROLES and RESPONSIBILITIES**

### **3.1**

The Institutional Biosafety Committee (IBC) is a University-wide committee charged with formulating policy and procedures related to the use of biohazardous agents, including: human pathogens, oncogenic viruses, other infectious agents, and recombinant DNA. The IBC is responsible for review and approval of projects involving recombinant DNA research and biohazardous materials. The committee sets containment levels in accordance with National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC) guidelines, and adopts emergency plans covering accidental spills and personnel contamination. The Vice Provost for Research appoints members of the IBC.

### **3.2**

The Office of Environmental Health and Radiation Safety (EHRS) is the operational arm of the IBC. It provides instruction and training on safe work practices, conducts routine inspections of work areas, investigates accidents and recommends preventive/corrective actions, reviews animal research protocols involving hazardous materials, reviews construction design for safety features and responds to emergencies.

### **3.3**

The Institutional Biosafety Officer (BSO) is an EHRS staff member and is responsible to oversee the daily implementation of the Biosafety Program. The BSO is responsible for development and review of the Biological Safety Manual, and other related documents, development of infectious waste disposal policies and procedures to comply with state regulations and plans for emergency response to accidental biohazard spills and personnel contamination. The BSO and the Biosafety staff perform periodic laboratory inspections, investigate laboratory accidents, and provide training and technical advice to Principal Investigators and staff on research safety procedures. The BSO also reports violations of the NIH Guidelines to the IBC.

### **3.4**

The Office of Regulatory Affairs is responsible for administering the University of Pennsylvania's compliance programs in the areas of human subjects (Institutional Review Board) and the care and use of animals in research (Institutional Animal Care and Use Committee).

### **3.5**

The Facilities Department in each school is responsible for the removal, packaging, and shipment of all infectious waste in accordance with local, state, and federal regulations.

### **3.6**

The Principal Investigator (PI) is responsible for full compliance with approved research protocols, the University Biological Safety Manual, the NIH Recombinant DNA Guidelines, the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standard (human-derived materials) and other local, state and federal regulations that apply to research.

## 4.0 PROCEDURES

### 4.1 Protocols

PIs are responsible for initiating research projects to be reviewed by the IBC and/or EHRS for work with recombinant DNA or biohazards. PIs are responsible for completing registration forms to be reviewed for work with recombinant DNA or biohazards. Upon submission of the forms, in accordance with the IBC and NIH Guidelines, the IBC and/or EHRS reviews the projects. The Biosafety staff performs an inspection of the facility and reviews work practices. In some cases (i.e. BSL 3 projects, use of Select Agents) Standard Operating Procedures (SOP's) are required to be submitted by the PI prior to obtaining IBC/EHRS approval.

### 4.2 Registration Forms

Prior to initiation of work with recombinant DNA or biohazards, the Principal Investigator must complete the appropriate registration forms and submit the completed forms to EHRS for IBC approval.

### 4.3 [Training](#)

The University of Pennsylvania's Biosafety Manual and the Exposure Control Plan describe the training requirements for personnel whose research involves recombinant DNA or biohazards. The BSO and Biosafety staff conduct biosafety training in accordance with applicable local and federal requirements.

### 4.4 Laboratory Audits

As part of the EHRS laboratory audit program, the Biosafety staff participates in laboratory inspections on an annual basis. The Biosafety staff audits laboratories that generate recombinant DNA and newly approved BSL2 labs. The Biosafety staff also audits HIV research laboratories and BSL3 labs semi-annually.

### 4.5 Recordkeeping

IBC project approval records are maintained by EHRS in accordance with federal standards. Laboratory inspection results and training attendance records are maintained by EHRS in accordance with applicable federal regulations. Principal Investigators are responsible for updating IBC-approved projects with EHRS, and providing current listings of personnel involved in IBC- approved projects.

### 4.6 Spills and Emergencies

The PI and/or lab personnel are responsible for initiating cleanup and disinfection in the event of a biohazard spill in a laboratory. Once the material has been contained, absorbed, and removed, housekeeping/Facilities management should be contacted to finalize the cleanup and disinfection of the area. The PI is responsible for ensuring that all corrective actions and emergency procedures are followed in accordance with applicable University procedures and regulations.

### 4.7 Infectious Waste

Infectious waste ("red bag waste") is sorted by the generator and disposed in a color-coded containers (usually red) marked with the universal biohazard symbol. All infectious waste sharps must be discarded in appropriate sharps disposal containers. Infectious waste red bags must be kept in a leak-proof container, closed when full, and placed in a designated area for decontamination. Laboratory personnel must decontaminate all infectious waste generated in laboratories before it is removed and packaged for transport by the individual school's Facilities Department. All infectious waste is incinerated by the University's infectious waste hauler and is managed in accordance with local, state, and federal regulations.

## 5.0 KEY REFERENCES

The following references and resources may be obtained from the Office of Environmental Health and Radiation Safety and are available on the EHRS website at [www.ehrs.upenn.edu](http://www.ehrs.upenn.edu)

[University of Pennsylvania Biological Safety Manual](#)  
[Infectious Waste Disposal Guidelines](#)

[University of Pennsylvania Exposure Control Plan](#)

[Biosafety in Microbiological and Biomedical Laboratories \(CDC-NIH\) 5th ed. 2009](#)

[OSHA 29 CFR 1910.1030 Bloodborne Pathogen Standard](#)

[Selection, Installation and Use of Biological Safety Cabinets \(CDC-NIH\)](#)

[WHO Biosafety Manual, 3rd. Ed.](#)