UW POLICY DIRECTORY

Rescinded 11-17-25

APS 12.3 – Review of Research Projects Involving Biological Hazards and Recombinant DNA

(Approved by the Executive Director of Health Sciences Administration by authority of Executive Order No. 1)

1. Overview

This policy statement establishes responsibilities for the identification, classification, and control of biological hazards (biohazards), and use of recombinant DNA associated with the University's vivaria and research, clinical, and teaching laboratories. Included are guidelines for students, staff, and faculty with information that is necessary to comply with regulatory requirements and to protect them and the surrounding community from possible hazards associated with the use of potentially hazardous biological agents and/or by-products, and recombinant DNA molecules.

For a more detailed discussion of procedure and requirements, refer to the University's Biosafety Manual located in laboratories conducting biological/recombinant DNA research and on the Environmental Health and Safety website.

A. Biohazards Definition

Biohazards include:

- Pathogenic agents (bacteria, rickettsia, fungi, viruses, protozoa, parasites, prions, and select agents).
- Plants, animals or derived waste which contain or may contain pathogenic hazards (including xenotransplantation tissue).
- Human and nonhuman primate tissue, body fluid, and cell culture (primary or continuous).
- Administration of hazardous materials to animals.
- Other animal tissues and body fluids.

B. Recombinant DNA Molecules Definition

Recombinant DNA molecules include: recombinant DNA molecules, and organisms and viruses containing recombinant DNA molecules. Recombinant DNA molecules are defined as either molecules which are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or DNA molecules that result from replication of those molecules described above.

2. Responsibility for Biological Safety

It is the University's policy that planning and implementation of control measures will be a part of every laboratory activity in which hazardous materials are used. Responsibility for the control of biohazards/recombinant DNA and the safety of employees and the public rests with the following individuals and groups:

A. Principal Investigators

The primary responsibility for establishing, following, and enforcing rules, procedures, and methods for the proper control of biohazardous agents, organisms, and recombinant DNA rests with the principal investigator.

The principal investigator is responsible for seeing that employees are adequately trained in safety practices. The principal investigator and/or laboratory supervisor is responsible for correcting work errors, identifying defective work conditions which could result in personal injury, and developing a positive attitude among employees toward accident prevention.

Each principal investigator is responsible for preparation of a safety plan for any research under his or her direction, which should include a description of the emergency procedures to be followed in the event of an accident.

B. Deans, Directors, Chairs, and Organizational Supervisors

Supervisors are responsible for all employees, students, faculty, and visitors in their areas of control. They must be aware of the hazards of research and approve control methods used by the principal investigator.

C. The Environmental Health and Safety Department

The Environmental Health and Safety Department is responsible for evaluating existing and potentially biohazardous conditions at the University, establishing safety standards, and providing staff support to the Institutional Biosafety Committee.

D. The University of Washington Institutional Biosafety Committee

On January 11, 2002 the Biosafety Committee and Recombinant DNA Committee merged to become the University of Washington Institutional Biosafety Committee. This committee is responsible for advising the Executive Director for Health Sciences Administration and the Director of EH&S, in establishing standards, providing consultant services, reviewing research proposals for compliance with standards, approving or disapproving these proposals, and recommending training and education methods for laboratory personnel.

3. Identification and Control of Biohazards

A. Rules, Regulations, and Guidelines

The following rules, regulations, and guidelines govern the use of biohazards and recombinant DNA molecules at the University:

- University of Washington Biosafety Manual.
- National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules.
- Center for Disease Control and National Institutes of Health—Biosafety in Microbiological and Biomedical Laboratories.
- Washington State Occupational Exposure to Bloodborne Pathogens (Chapter 296-823 WAC).
- Washington Industrial Safety and Health Act (Chapter 49.17 RCW).
- Seattle-King County Biomedical Waste Regulations (including sharps).

B. Standards for the University's Physical Facilities

Organizational units engaged in biohazardous activities must ensure that their physical facilities meet or exceed the requirements described for the safe handling, storage, and disposal of biohazardous substances as described in the documents listed above, as well as the physical standards for University facilities noted in the current edition of the UW EH&S Laboratory Safety Design Guide, particularly Chapter 7, "Biosafety Laboratories," and the UW Facility Design Information Manual, current edition.

C. Disposal of Biological Wastes

For specific information, refer to the University's Biosafety Manual.

4. Employee Occupational Health Program

Employee Occupational Health requirements and considerations are dependent upon the biohazards to which the employee may be exposed.

A. Employee Health Services

The Occupational Health Nurses at EH&S screen written protocols and the Research Protocol Hazard Assessment form for research related risks, including those associated with animals. Specific requirements for personal and laboratory-based protections are determined by the potential for exposures to chemical, biological, or physical hazards. When necessary, referrals for immunizations and/or other clinically-based medical services are made to the appropriate Campus Health Service's Employee Health Clinic, located at Hall Health Center, the University of Washington Medical Center, and/or Harborview Medical Center.

B. Immunization Guidelines

Specific immunizations are required for persons who have the potential to be exposed to certain biological agents or to come in contact with certain animals. The exact immunizations or other measures required are determined on an individual basis. Consultation on immunization requirements is arranged through the EH&S Occupational Health Nurse.

C. Serum Banking

Serum banking may be required when there is potential for exposure to biological agents or when there is contact with infectious animals. The UW Institutional Biosafety Committee has delegated specific serum banking requirements and decisions to the EH&S Occupational Health Nurse.

5. Review of Grant and Contract Proposals

All grant and contract proposals that involve any use of or exposure to potential biohazards and recombinant DNA as defined above, must be reviewed by the Institutional Biosafety Committee prior to submittal to the granting agency. For prompt committee action, the procedure for submissions should be reviewed, as outlined in the University's Biosafety Manual.

6. Safety Training

Principal investigators and/or organizational units engaged in biohazard and/or recombinant DNA activities must ensure that all laboratory staff, faculty, students, and employees participate in training programs appropriate to the potential biohazard in their unit or laboratory. EH&S provides training programs that emphasize safe work practices and precautionary measures which minimize the possibility of exposure. See the Training page of the EH&S website for specific courses offered.

All investigators, laboratory personnel, and students subject to potential exposure are expected to participate in the training programs. In addition, principal investigators must provide training which supplements the training provided by EH&S and is specific to the lab and/or subject of study.

May 1994; July 13, 2006.

Edit