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A. Purpose of Manual

This manual has been prepared to provide students, staff and faculty at the University of Washington with information that is necessary to protect them and the surrounding community from possible hazards associated with the use of biological agents and/or by-products and recombinant DNA molecules.

For the purpose of this manual potentially hazardous biological agents and by-products are called **biohazards**. 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 non-human primate tissue, body fluid, and cell culture (primary or continuous)
- Administration of hazardous materials to animals
- Other animal tissues and body fluids

Recombinant DNA molecules include molecules 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 the replication of those molecules described above.

This manual also includes guidelines for containment of biohazards to control the spread of contamination. The control practices contained in this manual are meant to supplement conventional safety efforts including accident and fire prevention.

Refer to the [UW Radiation Safety Manual](#) and the [UW Laboratory Safety Manual](#) for additional laboratory safety guidelines.

B. Incidence and Severity of Laboratory-Associated Infections

Research and clinical laboratories are work environments that pose unique risks to persons working in or near them. Personnel have contracted infections in the laboratory throughout history. Published reports around the turn of the century described laboratory-associated cases of typhoid, cholera, glanders, brucellosis and tetanus.

Meyer and Eddie published a survey of 74 laboratory-associated brucellosis infections in 1941. In the survey they attributed a number of cases to carelessness or poor technique in the handling of infectious materials.

Sulkin and Pike published a series of surveys of laboratory-associated infections summarizing viral infections. In their first survey published in 1949 they listed the probable source of at least a third of these infections to be associated with handling of infected animals and tissues. Known accidents were reported in only 12% (27 of 222) of the incidents.

Later Sulkin and Pike sent questionnaires on laboratory-associated infections to 5,000 laboratories. In 1951 they summarized the results of this survey:

1. Of the 1,342 laboratory-associated infections cited only a third had been previously reported in literature.
2. Brucellosis outnumbered all other laboratory-acquired infections.
3. Brucellosis, tuberculosis, tularemia, typhoid and streptococcal infection accounted for 72% of all bacterial infections.
4. Only 16% of all infections were associated with a documented accident. The majority of accidents were related to mouth pipetting and the use of a needle and syringe.

This survey was updated in 1965 and again in 1976. In the 1976 survey fewer than 20% of all cases were associated with a known accident. Exposure to infectious aerosols was considered to be the likely but unconfirmed source of infections.

In his 1979 review Pike concluded that "the knowledge, the techniques and the equipment to prevent most laboratory infection are available".

The booklet, *Classification of Etiologic Agents on the Basis of Hazard (1969)*, contained the concept of categorizing infectious agents and laboratory activities into four classes or levels. This format would later be used in the *NIH Guidelines for Research Involving Recombinant DNA Molecules* and the *CDC/NIH*

publication Biosafety in Microbiological and Biomedical Laboratories. The later was published in 1984 and updated in 1999. These publications provide the background for this manual.

In the 1980's and early 1990's additional regulations were passed in the United States, State of Washington, and King County/City of Seattle due to the increased public awareness of occupational exposure to bloodborne pathogens when dealing with human blood and body fluids. These regulations are covered in the following section.

C. Rules, Regulations and Guidelines Governing Use of Biohazards and Recombinant DNA Molecules

The following is a brief summary of the regulatory authorities that either regulate or provide guidelines for the use of biohazards.

1. [National Institutes of Health Guidelines](#) for Research Involving Recombinant DNA Molecules

In the early 1970's the National Institutes of Health (NIH) established a committee to provide advice on recombinant DNA technology. The NIH Guidelines which were announced on June 23, 1976 established carefully controlled conditions for conducting experiments involving recombinant DNA molecules. These guidelines describe the role and responsibility of the institution. Included is a requirement for the institution to establish an Institutional Biosafety Committee with authority to approve or disapprove proposed research based on an evaluation of available containment facilities and the scientific appropriateness of the proposal, using the NIH Guidelines as a minimum standard.

2. [Biosafety in Microbiological and Biomedical Laboratories](#)

In 1984 the Centers for Disease Control and National Institutes of Health published Biosafety in Microbiological and Biomedical Laboratories. This publication was updated in 1999 and provides specific descriptions of combinations of microbiological practices, laboratory facilities, safety equipment and recommendations for the use in the four biosafety levels of laboratory operation with selected infectious agents of man.

3. [The Select Agent Rule](#)

The Centers for Disease Control and Prevention is required to regulate the possession of biological agents and toxins that have the potential to pose a severe threat to public health and safety. CDC's Select Agent Program oversees these activities. The Select Agent Program currently requires registration of facilities including government agencies, universities, research institutions, and commercial entities.

4. [Washington Industrial Safety and Health Act](#)

Under provisions of the Washington Industrial Safety and Health Act (WISHA) occupational safety and health standards are promulgated by the

Department of Labor and Industries as chapters of the Washington Administrative Code (WAC). It is the intent of the University of Washington to comply fully with the standards and regulations developed by the Department of Labor and Industries.

[Bloodborne Pathogen Standard:](#)

WAC 296-62-080 as amended in April of 1992 is a duplicate of the Bloodborne Pathogen Standard promulgated by OSHA. This section of the WAC is found in its entirety in Section IX of this manual.

[Accident Prevention:](#)

WAC 296-24-14011 contains requirements for accident prevention tags (signs) used to identify hazardous conditions.

For the purpose of this section the term "biological hazard" or biohazard means those infectious agents presenting a risk of death, injury or illness to employees.

Biological hazard tags shall be used to identify the actual or potential presence of a biological hazard and to identify equipment, containers, rooms, experimental animals, or combinations thereof, that contain or are contaminated with hazardous biological agents.

The tag must be of the design specified in Figure J-15 of the regulations.

5. [Seattle Municipal Code Infectious Waste Management](#)

In 1989, the City of Seattle and the King County Board of Health adopted SMC 21.43, regulations on infectious waste management. Included in these regulations are requirements for a waste management plan to include a policy on storage and containment of infectious waste, infectious waste treatment, disposal including special disposal requirements for needles and other sharps waste and transportation of this type of waste. These regulations were updated in 1992 with the major change being the change in terminology from infectious waste to biomedical waste.

6. [Washington State Definition of Biomedical Waste, RCW 70.95K.010](#)

In 1992, the Washington State legislature adopted a statewide definition of biomedical waste that preempted any definitions previously established by individual local health departments or governments. This definition is the minimum requirement for defining infectious (biomedical) waste in the state of Washington:

- a. "Animal waste" is waste animal carcasses, body parts, and bedding of animals that are known to be infected with, or that have been inoculated with, human pathogenic microorganisms infectious to humans.
- b. "Biosafety Level 4 disease waste" is waste contaminated with blood, excretions, exudates, or secretions from humans or animals who are isolated to protect others from highly communicable infectious diseases that are identified as pathogenic organisms assigned to Biosafety Level 4 by the Centers for Disease Control, National Institutes of Health, Biosafety in Microbiological and Biomedical Laboratories, current edition.
- c. "Cultures and stocks" are wastes infectious to humans and includes specimen cultures, cultures and stocks of etiologic agents, wastes from production of biologicals and serums, discarded live and attenuated vaccines, and laboratory waste that has come into contact with cultures and stocks of etiologic agents or blood specimens. Such waste includes but is not limited to culture dishes, blood specimen tubes, and devices used to transfer, inoculate, and mix cultures.
- d. "Human blood and blood products" is discarded waste human blood and blood components, and materials containing free-flowing blood and blood products.
- e. "Pathological waste" is waste human source biopsy materials, tissues, and anatomical parts that emanate from surgery, obstetrical procedures, and autopsy. "Pathological waste" does not include teeth, human corpses, remains, and anatomical parts that are intended for interment or cremation.
- f. "Sharps waste" is all hypodermic needles, syringes with needles attached, IV tubing with needles attached, scalpel blades, and lancets that have been removed from the original sterile package.

D. University Policy

The University of Washington has an established policy on safety programs.

The University shall create, maintain and enhance a safe and healthful environment for all individuals associated with the institution, including students, faculty, staff employees, hospital patients and visitors. Environmental health and safety activities and procedures shall be administered so as to achieve the highest ethical and professional standards in accord with legal and contractual requirements. Accident prevention measures shall be integrated in all academic and operational activities.

Each dean, director, chairperson and supervisor is responsible for safety performance in their respective units. The Department of Environmental Health and Safety will provide technical assistance in establishing procedures and monitoring performance in activities involving public health and safety and environmental protection.

Because of the personal nature of safety performance, everyone with supervisory responsibility will be expected to directly participate in the supervision of programs to assure that safe working conditions are maintained. Faculty and staff shall be directly responsible for their own safety, for the safety of students and employees under their supervision, and for the safety of their fellow employees. This responsibility can neither be transferred nor delegated. Supervisors shall provide training for accident prevention, as necessary, for those working under their direction. (University of Washington Handbook [Volume Four, Part VI, Chapter 4: University Safety Programs](#))

E. The Biosafety Committee

On January 11, 2002 the Biosafety Committee and Recombinant DNA Committee merged to become The University of Washington Institutional Biosafety Committee.

Recognizing that the federal government was preparing regulations concerning biohazardous research which would affect research grants and proposals, the Executive Director for Health Sciences Administration appointed an Ad hoc Biohazard Safety Committee on April 18, 1973. This Ad hoc committee recommended that a permanent committee be appointed. On May 20, 1974, a permanent Biohazard Safety Committee was appointed with the following charge (as amended July 1, 1992):

1. *To recommend on a continuing basis policies pertaining to biological research in accord with federal, state and local regulations, to the Board of Environmental Health and Safety for review and adoption.*
2. *To establish, review and revise guidelines pertaining to biological laboratory facilities, work practices and equipment inspection and maintenance, under which research involving biohazardous agents is carried out at the University of Washington. Guidelines developed will meet or exceed federal, state and local requirements.*
3. *To review all proposed research forwarded to Grant and Contract Services involving pathogenic organisms; human or animal blood, cells, tissues or body fluids, or animal species with the potential to carry organisms pathogenic to humans in order to determine whether such proposals meet the established guidelines. Pilot and preliminary experiments are reviewed when requested by the investigator.*
4. *To recommend to the Executive Director for Health Sciences Administration approval or disapproval of all research proposals reviewed, based on compliance with established policies and guidelines and weighing the potential benefits against the probable risk.*
5. *To periodically review all ongoing biohazardous research to ensure its conformity to established guidelines and to approve or disapprove its continuance on the basis of review findings.*
6. *To advise the Executive Director for Health Sciences Administration and the Director of Environmental Health and Safety with respect to such programs and facilities as are necessary to establish and maintain conditions that conform to the established guidelines.*
7. *To maintain close and continuous liaison with the Recombinant DNA Committee.*

F. UW Recombinant DNA Committee

On January 11, 2002 the Biosafety Committee and Recombinant DNA Committee merged to become The University of Washington Institutional Biosafety Committee.

Because of the potential hazards that accompany research on recombinant DNA molecules and recognizing that the federal government was preparing guidelines concerning recombinant DNA research, the Executive Director for Health Sciences Administration appointed an Ad hoc Recombinant DNA Committee on June 1, 1976. This Ad hoc committee recommended formation of a permanent committee which was appointed on February 11, 1977. As amended July 1, 1992 the charge to the Committee is as follows:

- 1. To establish, review and revise guidelines under which research involving recombinant DNA is carried out at the University of Washington. These guidelines to include such considerations as scientific value and appropriateness, socioethical ramifications and environmental impact. The NIH Guidelines are to be considered minimum standard; guidelines that are more stringent may be adopted by the University of Washington.*
- 2. To review all proposed recombinant DNA research at the University of Washington, regardless of funding source, in order to determine whether such proposals meet with the established guidelines.*
- 3. To recommend to the Executive Director for Health Sciences Administration approval or disapproval of any proposal involving recombinant DNA, weighing the potential benefits of each project against the probable risk.*
- 4. To periodically review all on-going recombinant DNA research to ensure its conformity, to establish guidelines and to recommend to the Executive Director for Health Sciences Administration approval or disapproval of its continuance on the basis of the review findings.*
- 5. To advise the Executive Director for Health Sciences Administration and the Director of Environmental Health and Safety with respect to such programs and facilities as are necessary to establish and maintain conditions that conform to the established guidelines.*
- 6. To maintain close and continuous liaison with the Biosafety Committee.*
- 7. To assure that the University of Washington is otherwise functioning in accord with the NIH Recombinant DNA Guidelines*

U.W. Institutional Biosafety Committee Members

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G. General Policies for Control in Biohazard and Recombinant DNA Laboratory Work

Responsibility

The responsibility for the control of biohazards and the safety of employees and the public rests with:

- a. **Principal Investigator.** At the University of Washington the primary responsibility for establishing, following and enforcing rules, procedures and methods for the proper control of biohazardous agents and organisms 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 working conditions which could result in personal injury, and developing a positive attitude among employees toward accident prevention.

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

Each principal investigator and/or laboratory supervisor is responsible for reporting and initiating the investigation of any accident/incident, initiation of corrective action and recommendation of improvements that will insure maximum safety for his/her employees. (University of Washington Administrative Policy Statements [12.03](#), [10.03](#), and [10.08](#))

- b. Deans, Directors, Chairpersons and Organizational Supervisors.** These supervisors are responsible for all employees, students 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. All accidents must be reviewed by the chairperson and any necessary steps taken to ensure conditions and methods are changed as soon as practical after the accident. (University of Washington Administrative Policy Statements 12.03 and 10.03)
- c. The Department of Environmental Health and Safety.** This department is responsible for evaluating existing and potential biohazardous conditions at the University of Washington, establishing safety standards and providing staff support to the Biohazard Safety and Recombinant DNA Committees. (University of Washington Administrative Policy Statements [12.03](#) and [10.01](#))
- d. The Institutional Biosafety Committee (IBC).** IBCs were originally established under the NIH Guidelines for Research Involving Recombinant DNA Molecules to provide local, institutional oversight of nearly all forms of research utilizing recombinant DNA. Over time, however, the role of the IBCs has been expanded to include review and oversight of a variety of experimentation that involves biological materials (e.g., infectious agents) and other potentially hazardous agents (e.g., carcinogens). At the University of Washington the IBC is responsible for advising the Executive Director for Health Sciences Administration and Director of Environmental Health and Safety, particularly in the areas of 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. (University of Washington Administrative Policy Statements [12.03](#) and [10.03](#)) The National Institute of Health's Office of Biotechnology Activities (OBA) website details the [IBC's Roles and Responsibilities](#).

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