## **ENVIRONMENTAL HEALTH & SAFETY**

UNIVERSITY of WASHINGTON

## **BIOSAFETY MANUAL**

NOVEMBER 2021

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#### **FORWARD**

This policy and procedures manual was developed by the University of Washington Environmental Health and Safety (EH&S) Department to provide information to protect workers and the surrounding environment and to achieve compliance with applicable standards and regulations. The University of Washington Institutional Biosafety Committee (IBC) approved this revision with the expectation that updates will be necessary as changes in regulations, policies and procedures dictate.

The premise is that safety is a top priority for all experiments. Planning for and implementation of biohazard controls to prevent laboratory-associated infections and to control the spread of contamination must be a part of every laboratory activity in which biohazardous agents, including recombinant or synthetic DNA/RNA, are used.

The handling of biohazardous agents, including recombinant or synthetic nucleic DNA/RNA, requires the use of various precautionary measures depending on the agent(s) involved. It is the purpose of this manual to provide general guidelines for evaluation, containment, and control of biohazards, categorized as to degree of risk of infection.

Implementation of these policies and procedures is the responsibility of the Principal Investigator and depends largely on the efforts of laboratory supervisors and employees. It is essential that they seek additional advice and training when needed to conduct research in a manner that is safe to employees, students, and the surrounding community. To assist in this endeavor, the services of the Environmental Health and Safety Department are available at the University of Washington.

First Edition – July 1978

Second Edition - January 1993

Updated – July 1997

Administrative Changes – January 2003

Updated - March 2013

Updated - October 2014

Updated - January 2017

Updated - February 2018

Updated - January 2019

Updated - September 2019

Updated - November 2021 (log of changes)



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## **EMERGENCY INFORMATION**

	Telephone
Principal Investigator/Supervisor:	
Building Coordinator:	
Custodial or Environmental Services:	
University of Washington (UW) Police (On Campus)	911
Seattle Fire Department (On Campus)	911
Employee Health Center	
Seattle Campus, South Lake Union	206-685-1026
Harborview	206-744-3081
Environmental Health and Safety (EH&S)	
EH&S Main Office	206-543-7262
Research and Occupational Safety Section	206-221-7770

## AFTER HOURS, WEEKENDS AND HOLIDAYS

UW Police (On Seattle Campus)	911
Seattle Fire (On Seattle Campus)	911
Environmental Health and Safety Staff-On-Call	Page through 206-685-UWPD

#### WHEN REPORTING A BIOHAZARD EMERGENCY

- 1. State that this is a Biohazard Emergency
- 2. Give Your Name
- 3. Give Your Location (Room and Building)
- 4. Give the Phone Number You Are Using
- 5. Describe the Nature of the Emergency
- 6. Report Personal Injury or Threat of Injury



## **SECTION 1 – INTRODUCTION**

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#### A. PURPOSE OF THE MANUAL

This manual has been prepared for the purpose of providing students, staff, and faculty at the University of Washington (UW) with information that is necessary to protect them and the surrounding community from possible hazards associated with the use of biohazardous agents and recombinant or synthetic DNA/RNA (recDNA) molecules. This manual's guidance is intended for work with biohazards in approved University locations. Biohazards at the University are not permitted to be taken off campus to a private residence or for other purposes not related to or approved for institutional use. Refer to the <a href="UW Laboratory Safety Manual">UW Radiation Safety Manual</a> for additional laboratory safety guidelines.



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#### **B. DEFINITION OF BIOHAZARDS**

For the purpose of this manual, potentially hazardous biological agents and by-products are called biohazardous agents. The UW IBC's working definition of a biohazardous agent includes the following:

- 1. Pathogenic agents (bacteria, rickettsia, fungi, viruses, protozoa, parasites, prions, and Select Agents)
- 2. Recombinant or synthetically derived nucleic acid, including those that are chemically or otherwise modified analogs of nucleotides (e.g., morpholinos) or both. The NIH defines synthetically derived nucleic acid molecules as follows:
  - a. Molecules that (a) are constructed by joining nucleic acid molecules and (b) can replicate in a living cell (i.e., recombinant nucleic acids);
  - b. Nucleic acid molecules that are chemically or otherwise modified but can pair with naturally occurring nucleic acid molecules (i.e., synthetic nucleic acids);
  - c. Molecules that result from the replication of those described in (a) or (b) above
- 3. Recombinant DNA molecules, organisms, vectors (e.g., plasmids, viral vectors), and viruses containing recombinant DNA molecules
- 4. Human and non-human primate blood, tissue, body fluid, and cell culture (primary and established cell lines)
- 5. Plants, animals, or derived waste which contains or may contain pathogenic hazards (including xenotransplantation tissue)

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

#### C. THE OCCURRENCE 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.

The following information on the occurrence of Laboratory-Associated Infections (LAIs) in clinical (diagnostic) and research laboratories is taken from Section I of the Centers for Disease Control and Prevention (CDC)/National Institutes of Health (NIH) publication, Biosafety in Microbiological and Biomedical Laboratories (BMBL).

Published reports of LAIs first appeared around the start of the twentieth century. By 1978, four studies by Pike and Sulkin collectively identified 4,079 LAIs resulting in 168 deaths occurring between 1930 and 1978. These studies found that the ten most common causative agents of overt infections among workers were *Brucella* spp., *Coxiella burnetti*, hepatitis B virus (HBV), *Salmonella typhi*, *Francisella tularensis*, *Mycobacterium tuberculosis*, *Blastomyces dermatitidis*, Venezuelan equine encephalitis virus, *Chlamydia psittaci*, and *Coccidiodes immitis*. The authors acknowledged that the 4,079 cases did not represent all LAIs that occurred during this period since many laboratories chose not to report overt cases or conduct surveillance programs to identify sub-clinical or asymptomatic infections.



In addition, reports of LAIs seldom provided data sufficient to determine incidence rates, complicating quantitative assessments of risk. Similarly, there were no distinguishable accidents or exposure events identified in more than 80% of the LAIs reported before 1978. Studies did show that in many cases the infected person worked with a microbiological agent or was near another person handling an agent.

During the 20 years following the Pike and Sulkin publications, a worldwide literature search by Harding and Byers revealed 1,267 overt infections with 22 deaths. Five deaths were of fetuses aborted as the consequence of a maternal LAI. *Mycobacterium tuberculosis, Coxiella burnetii*, hantavirus, arboviruses, HBV, *Brucella* spp., *Salmonella* spp., *Shigella* spp., hepatitis C virus (HCV), and *Cryptosporidium* spp. accounted for 1,074 of the 1,267 infections. The authors also identified an additional 663 cases that presented as sub-clinical infections. Like Pike and Sulkin, Harding and Byers reported that only a small number of the LAI involved a specific incident. The non-specific associations reported most often by these authors included working with a microbiological agent, being in or around the laboratory, or being around infected animals.

The findings of Harding and Byers indicated that clinical (diagnostic) and research laboratories accounted for 45% and 51%, respectively, of the total LAIs reported. This is a marked difference from the LAIs reported by Pike and Sulkin prior to 1979, which indicated that clinical and research laboratories accounted for 17% and 59%, respectively. The relative increase of LAIs in clinical laboratories may be due in part to improved employee health surveillance programs that are able to detect sub-clinical infections, or to the use of inadequate containment procedures during the early stages of culture identification.

Comparison of the more recent LAIs reported by Harding and Byers with those reported by Pike and Sulkin suggests that the number of LAIs is decreasing. Harding and Byers note that improvements in containment equipment, engineering controls, and greater emphasis on safety training may be contributing factors to the apparent reduction in LAIs over two decades. However, due to the lack of information on the actual numbers of infections and the population at risk, it is difficult to determine the true incidence of LAIs.

Publication of the occurrence of LAIs provides an invaluable resource for the microbiological and biomedical community. For example, one report of occupational exposures associated with *Brucella melitensis*, an organism capable of transmission by the aerosol route, described how a staff member in a clinical microbiology laboratory accidentally sub-cultured *B. melitensis* on the open bench. This error and a breech in containment practices resulted in eight LAIs with *B. melitensis* among 26 laboratory members, an attack rate of 31%. Reports of LAIs can serve as lessons in the importance of maintaining safe conditions in biological research.

# D. RULES, REGULATIONS AND GUIDELINES GOVERNING THE USE OF BIOHAZARDS AND recDNA MOLECULES

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



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## NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

In the early 1970s, the NIH established a committee to provide advice on recDNA technology. The NIH Guidelines, which were announced on June 23, 1976, and which continue to be updated, established carefully controlled conditions for conducting experiments involving recDNA molecules. These guidelines describe the roles and responsibilities of the Institution, the IBC, and the Principal Investigator (PI).

#### 2. CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)

In 1984, the CDC and NIH published <u>BMBL</u>. The publication was last updated in 2020 and provides specific descriptions of combinations of microbiological practices, laboratory facilities, safety equipment, and recommendations for use in the four biosafety levels of laboratory operation with selected human infectious agents and biological toxins.

#### 3. The Select Agent Rule

The CDC 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. The CDC's <u>Federal Select Agent Program oversees these activities</u>. 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 <u>Washington Industrial Safety and Health Act (WISHA)</u>, 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 UW to comply fully with the standards and regulations developed by the Department of Labor and Industries.

#### 5. Bloodborne Pathogens Standard

WAC 296-823, Occupational Exposure to Bloodborne Pathogens is an extension of the Bloodborne Pathogens Standard promulgated by the Federal Occupational Safety and Health Administration (OSHA). It applies to staff with reasonably anticipated exposure to blood or other potentially infectious materials (including human cell lines) during the course of their work.

#### 6. Seattle Municipal Code Infectious Waste Management

In 1989, the City of Seattle and the King County Board of Health adopted <u>SMC 21.43</u> covering regulations on infectious waste management. These regulations include requirements for a waste management plan that includes 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, the major modification being the change in terminology from infectious waste to biomedical waste. The University's Biohazardous Waste Management Plan is written per the requirements in this rule.

#### 7. Washington State Definition of Biomedical Waste

The Washington State legislature in <u>Chapter 70.95K</u> adopted a statewide definition of biomedical waste that preempts 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" consists of animal carcasses, body parts, and the bedding from animals that are known to be infected with or that have been inoculated with human pathogenic microorganisms infectious to humans.
- b. "Cultures and stocks" consist of wastes infectious to humans and include 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 in 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.
- c. "Human blood and blood products" are discarded human blood and blood components and materials containing free-flowing blood and blood products.
- d. "Pathological waste" consists of 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, or anatomical parts that are intended for interment or cremation.
- e. "Sharps waste" The term "sharps" is a regulatory waste classification associated with those instruments used to puncture, cut, or scrape body parts and that, in a waste container, can cause punctures or cuts to solid waste handlers or the public. This means that all sharps waste must be placed in appropriate sharps containers and decontaminated prior to disposal. Sharps include the following:
  - i. Needles, including syringes with needles and IV tubing with needles attached
  - ii. Lancets
  - iii. Scalpel blades
  - iv. Other sharps items not defined above only if contaminated with biohazardous material including recDNA (e.g., broken glass; razor blades; fragile glass tubes, vials, or ampoules including glass Pasteur pipettes; glass slides and cover slips)

#### 8. Department of Transportation

Department of Transportation <u>Title 49</u> regulations apply to all untreated biohazardous waste that is shipped off-site for treatment and disposal by a UW waste contractor. Employees who prepare biohazardous waste for collection by a waste contractor must complete mandatory EH&S training before offering shipments and every three years.

# 9. United States Government Policy for Institutional Oversight of Life Sciences DURC (Dual Use Research of Concern)

The Dual Use Research of Concern (DURC) policy aims to preserve the benefits of life sciences research, while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by the research. The <u>United States Government Policy</u> applies to research involving high consequence pathogens and toxins. If research with botulinum neurotoxins or a subset of select agents is anticipated to create categories of experimental concern, it is



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considered to be DURC. UW EH&S and the Institutional Biosafety Committee (IBC), with assistance from the Office of Research, are responsible for developing and implementing the <u>University's DURC policy</u>.

#### E. UNIVERSITY POLICY

The UW has an established policy on health and safety programs in <u>UW Presidential Order 55</u>, including:

The University of Washington is committed to providing a healthy and safe environment for faculty, staff, students, visitors, and volunteers in all sites owned, operated, or controlled by the University. This commitment includes supporting a culture of health and safety across the University...

The University President has the ultimate responsibility for health and safety programs for the University. Under the authority delegated by the President, the Provost, the vice presidents and vice provosts, chancellors, deans, directors, chairs and unit supervisors, including faculty supervising academic activities, are responsible for:

- Reinforcing the importance of health and safety and creating a culture of health and safety in their units;
- Providing oversight of facilities, equipment, and practices to support a safe work and academic environment;
- Ensuring individuals under their supervision have sufficient authority and support to properly implement health and safety regulations, policies, and procedures;
- Being aware of and following safety plans for all University workplaces, classrooms, laboratories, field work locations, and student life areas;
- Assuring compliance with mandatory health and safety training in their units;
- Acting in support of the Department of Environmental Health and Safety (EH&S) and units with related responsibilities (see Sections <u>5</u> and <u>6</u> below) to monitor adherence to applicable health and safety regulations, policies, and procedures; and
- Establishing priorities and committing resources for correction of health and safety deficiencies.

#### F. ROLES AND RESPONSIBILITIES FOR CONTROL OF BIOHAZARDOUS RESEARCH

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

#### 1. Principal Investigator (PI)

At the UW, the primary responsibility for establishing, following, and enforcing rules, procedures, and methods for the proper control of biohazardous agents and toxins, including the use of recDNA, rests with the PI.

The UW Institutional Biosafety Committee's (IBC) definition of a Principal Investigator for research projects involving biohazards is as follows. Refer to the <u>IBC charter</u> for more information.



The Principal Investigator is an individual who is designated and given the authority by a University department, school, or administrative unit to direct the research program or project. The PI has scientific and technical direction for the research. The PI has the responsibility and authority to enforce biosafety and biosecurity regulations and policies, including the NIH Guidelines. This includes ensuring that the facilities are appropriate for the research conducted and for ensuring that personnel who will be involved with the project are trained. Any Biological Use Authorization Application with an assigned PI who does not fall within this definition will be considered on a case-by-case basis.

The PI is responsible for ensuring all research with biohazardous agents, including recDNA, is reviewed and approved by the IBC and/or the EH&S Research and Occupational Safety (ROS). The PI must complete the EH&S Biosafety Training every three years if their research includes the use of biohazardous agents.

The PI must be adequately trained on the NIH Guidelines and laboratory specific procedures involving use of recDNA. The PI must be adequately trained in good microbiological techniques and is responsible for seeing that laboratory staff are adequately trained in safety practices. The PI is responsible for correcting work errors, identifying defective working conditions that could result in personal injury, and developing a positive attitude among laboratory staff toward accident prevention. The PI is responsible for informing the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection).

Performing an ongoing risk assessment and enforcing the process is a responsibility of the PI. The risk assessment process is comprised of a six part system:

- 1. Identify hazardous characteristics of the agent and perform an assessment of the inherent risk.
- 2. Identify laboratory procedural hazards.
- 3. Make a determination of the appropriate biosafety level and select additional precautions indicated by the risk assessment.
  - a. A PPE assessment is required for all research. Use the EH&S <u>PPE assessment</u> guide for reference.
  - b. A laboratory biosecurity risk assessment should be done and should focus on the prevention of theft, loss, and misuse of hazardous biological agents and toxins, equipment, and/or valuable information.
- 4. Before implementation of the controls, review the risk assessment and selected safeguards with a biosafety officer. IBC review may be needed for projects that fall under the NIH Guidelines.
- 5. As part of an ongoing process, evaluate the proficiencies of staff regarding safe practices and the integrity of safety equipment.
  - a. UW specific training can be accessed on the EH&S website. <u>Training course</u> <u>selection guides</u> are available. <u>Training records</u> for laboratory staff can be viewed by the PI.
- 6. Revisit regularly, verify risk management strategies, and determine if changes are necessary.

The PI is responsible for adhering to IBC-approved emergency plans for handling accidental spills and personnel contamination. The PI is also responsible for complying with shipping requirements for recDNA or other biohazardous materials.



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While conducting research, the PI is responsible for supervising the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed. The PI is responsible for investigating and reporting any significant problems pertaining to containment practices and procedures to EH&S and correcting any work errors and conditions that could result in the release of biohazardous agents, including recDNA.

UW-affiliated clinical investigators doing research with recDNA in human research participants have the responsibility to be familiar with the NIH Guidelines and ensure all aspects pertaining to NIH and local IBC review and reporting obligations are appropriately addressed. UW-affiliated clinical investigators must have Institutional Review Board (IRB) and IBC approval before enrolling subjects, regardless of the funding source or the molecular nature of the gene transfer reagent (plasmid or viral vector, vaccines).

#### 2. Department of Environmental Health and Safety (EH&S)

This department is responsible for evaluating existing and potential biohazardous conditions at the UW, establishing safety standards, and providing staff support to the IBC (UW Administrative Policy Statements 12.3 and 10.1).

#### a. EH&S Biosafety Officers

The EH&S Biosafety Officers (BSOs) have expertise in developing and supporting the Biosafety Program (including BSL-1, BSL-2, BSL-3 laboratories and select agents). They develop and implement policies, procedures and processes required for an effective, compliant and efficient biosafety program. They play a lead role in providing technical support to the UW IBC. They review research proposals, laboratory operations and laboratory facilities for all aspects of biosafety to assure appropriate safety controls, containment and compliance with federal, state and local regulatory agencies as well as seeing that UW requirements are met. They work closely with research staff, faculty, students, university units and institutional committees to promote safe laboratory practices, procedures, and proper use of containment equipment and facilities. They conduct compliance audits, identify corrective actions, and prepare written status and compliance reports. They develop and provide educational materials and training. They also respond to, investigate and follow up with biological safety incidents.

#### b. Employee Health Services

The Occupational Health Nurses (OHN) at EH&S screen written protocols and the Biological Use Authorization (BUA) application form for research-related risks, including those associated with animals. Specific requirements for personal and laboratory-based protections are determined by the potential for exposure 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 Center (EHC), located at Hall Health Center, the University of Washington Medical Center (UWMC) and/or Harborview Medical Center (HMC) (UW Administrative Policy Statement 12.3).

#### 3. Institutional Biosafety Committee (IBC)

IBCs were originally established under the NIH Guidelines to provide local institutional oversight for nearly all forms of research utilizing recDNA. Over time, however, the role of the IBCs has 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).



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The IBC is composed of an IBC Chair; Biosafety Officer; public members not affiliated with UW who represent the interest of the surrounding community with respect to health and protection of the environment; research faculty with adequate expertise and training in human gene transfer protocol reviews, in plant, plant pathogen or plant pest containment principles, and in animal containment principles in accordance with the NIH Guidelines. This committee is responsible for advising the Executive Office of the President & Provost and the Director of EH&S, in establishing standards, providing consultant services, reviewing research proposals for compliance with standards, approving or denying these proposals, and recommending training and education methods for laboratory personnel (UW Administrative Policy Statements 12.3). The IBC also reviews research protocols involving recDNA in human research participants. This review compliments the IRB review (UW Human Subject Division) as both are necessary prior to subject enrollment.

#### 4. Deans, Directors, Chairpersons, and Organizational Supervisors

These 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 PI (UW Administrative Policy Statements 12.3 and 10.3).

#### 5. Department of Comparative Medicine

The Department of Comparative Medicine is responsible for the operation and maintenance of centralized animal vivarium facilities including centralized Animal Biosafety Level 1 (ABSL-1), Animal Biosafety Level 2 (ABSL-2) and Animal Biosafety Level 3 (ABSL-3) facilities, excluding the Washington National Primate Center (WaNPRC).

#### 6. Washington National Primate Research Center

The WaNPRC is responsible for the operation and maintenance of all non-human primate (NHP) facilities.



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# SECTION 2 – REVIEW PROCEDURES FOR RESEARCH AT UW

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#### A. RESEARCH PROJECT REVIEWS

#### 1. Policy

Grant and contract proposals that involve any use of, or exposure to, potential biohazards, including recDNA, are reviewed by the IBC and/or EH&S. All such research proposals, regardless of funding source, are subject to this review. The IBC, not the investigator or department, is charged with the final determination of hazard classifications. Certain funding agencies also require the UW to assure the biosafety compliance of the PI with the submittal of the proposal.

#### 2. Procedures

#### a. Initiating Review

Project review is initiated when a PI submits the **BUA** application.

#### **b.** Approval Process

The information is reviewed by a BSO and/or the IBC, depending, in part, upon the project's complexity and risk. The BSO and/or the IBC may request additional information from the PI to aid in the review of the proposal. Incomplete applications may be returned to the PI. The PI will receive notification of IBC review and determination of approval or denial. If the notification letter indicates a conditional approval, it will also indicate actions or information that the IBC must receive before final approval notification can be issued.

Projects may be subject to other UW approvals such as IRB, Institutional Animal Care and Use Committee (IACUC), DURC; see Table 2-1. If the project involves animals, IACUC approval is always required prior to project initiation.

#### c. Renewals and Changes to Previously Approved Research

Additional IBC review and approval is required:

1) Every three years for projects involving biohazardous agents, including recDNA, and, if animal work is involved, concurrent with expiration of IACUC protocols. To renew the approval, PIs should submit a BUA application two months prior to the expiration date of their current BUA letter or animal protocol. PIs can check the BUA submission deadlines online.



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2) Before modifying or making any significant changes to a research protocol already approved by the IBC (e.g., any changes related to laboratory equipment that may generate aerosols, research procedures, lab locations, gene inserts, biohazardous agents, etc.). This is done by submitting a Request for Change to BUA form to the IBC.

## **B. LEVELS OF REVIEW REQUIRED FOR RECDNA RESEARCH**

Table 2-1 summarizes the types of approvals and reviews required from various boards and committees for the use of recombinant DNA research.

Table 2-1: Levels of Review Required for recDNA Research

NIH	Experiments covered under <u>NIH</u> <u>Guidelines</u>	NIH Approval	Institutional Approval/Review		
<i>Guidelines</i> Section			IBC Approval	EHS Review	IRB/IACUC Approvals
Section III-A	Transfer of drug resistance trait to a microorganism not known to acquire the trait naturally	YES (NIH Director)	YES		
Section III-B	Cloning of toxin molecules with LD50 less than 100ng/kg body weight	YES	YES		
Section III-C	Gene transfer into humans by recDNA		YES		IRB Contingent on IBC Approval
	recDNA in vaccines		YES		IRB Contingent on IBC Approval
Section III-D	Recombinant risk group 2, 3, or restricted agents as host-vector systems DNA is cloned into non-pathogenic prokaryotic or lower eukaryotic host-vector systems		YES		
	Infectious virus or replication defective virus in presence of helper virus in tissue culture systems (e.g., viral vectors)		YES		



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NIH Guidelines Section	Experiments covered under <u>NIH</u> <u>Guidelines</u>	NIH Approval	Institutional Approval/Review		
			IBC Approval	EHS Review	IRB/IACUC Approvals
	Whole transgenic animals and recDNA-modified microorganisms tested on whole animals		YES		IACUC
	recDNA modified whole plants		YES		
	More than 10 L of recDNA culture		YES		
	Influenza viruses (specific strains) generated by recombinant methods		YES		
	Those not above		YES		
Section III-E	Less than 2/3 eukaryotic virus genome		YES		
	recDNA modified whole non- pathogenic plants and plants associated microorganisms		YES		
	Generation of transgenic rodents that require BSL-1 containment		YES		
	Not in organisms, cells, or viruses			YES	
	Non-chromosomal or viral DNA of single source			YES	
Section III-F	Prokaryotic DNA with indigenous plasmids or viruses when propagated in same system or when transferred			YES	
	Eukaryotic DNA, propagated in same system			YES	
	Physiological exchangers			YES	
	Not a significant risk to health or environment			YES	

Note: For work with human embryonic stem cells (hESC) and induced pluripotent stem cells (iPS), contact the UW Embryonic Stem Cell Research Oversight Committee (ESCRO). These studies require IBC review when recDNA is involved.



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## SECTION 3 – BIOLOGICAL RISK ASSESSMENT

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	ROUTES OF EXPOSURE

#### A. BIOLOGICAL RISK ASSESSMENT

Risk assessment is a process used to identify the degree of risk to the laboratory worker, other personnel, and the environment. The degree of risk takes into consideration the virulence, pathogenicity, biological stability, and communicability of the organisms as well as the route of transmission. A biological risk assessment takes into account both the hazard characteristics of the biological agent and the laboratory procedure hazards.

If biological agents are genetically modified, the risk assessment must take into account how that modification may potentially change an agent's hazard characteristics such as virulence, pathogenicity or susceptibility to treatments. This information may not always be available for genetically modified organisms. Refer to the NIH Guidelines to aid in assessing risk for work involving recombinant or synthetic nucleic acids.

Part of the risk assessment should take into account the risk of exposure versus the risk of infection. Consider the main hazardous characteristics of the agent, which include its capability to infect and cause disease in a susceptible host, severity of disease, and the availability of preventive measures and effective treatments. Also, consider the possible routes of transmission of infection in the laboratory, the infectious dose, stability in the environment, host range, whether the agent is indigenous or exotic to the local environment, and the genetic characteristics of the agent. As part of this assessment, respiratory protection should be addressed for BSL-2 or higher agents.



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#### **B. ROUTES OF EXPOSURE**

Knowledge of the natural route of transmission for a biological agent or toxin can be used to identify potential routes of transmission in the laboratory. However, the route of transmission and the disease caused by a laboratory-acquired infection can be different from a naturally-acquired disease. This is because in the laboratory, infectious agents are often used at higher concentrations than may be encountered naturally and can be aerosolized during laboratory procedures although they are not naturally transmitted via the aerosol route.

#### 1. Oral Infection: Ingestion or Hand to Mouth Exposure

Enteric pathogens are often used in the microbiology lab and carry the prime risk of infection by ingestion. Examples are ova and parasites, *Salmonella typhimurium*, hepatitis A virus and enteropathogenic *E. coli* strains. Avoid touching the face during laboratory work. Face shields or face masks can be worn to protect the mouth. Good hand hygiene is essential. Always wash hands after gloves are removed and before leaving the laboratory.

#### 2. Parenteral Inoculation

A variety of agents are transmitted through parenteral inoculation or puncture such as arthropod-borne virus infections, protozoal infections (malaria), human immunodeficiency virus (HIV) and hepatitis B virus (HBV). However, bacterial agents that can cause septicemia can also cause infections if injected. Good sharps safety practices are needed to prevent needlesticks or other sharps injuries that can cause an exposure.

## 3. Direct Skin, Eye or Mucosal Membrane Exposure

Several agents enter the body through the skin, eyes or mucous membranes. Mucous membranes include the nose, mouth, throat and genitals. Agents that spread this way include herpes simplex viruses and *Staphylococcus aureus* skin infections. Most bloodborne pathogens can infect via exposure to the eyes or mucous membranes. To protect yourself in the lab, wear clothes that cover the skin in addition to a lab coat and gloves. Safety glasses, goggles, face masks and face shields can be worn to protect the eyes and mucous membranes.

#### 4. Inhalation of Infectious Aerosols

A variety of agents infect by the respiratory route including *Mycobacterium tuberculosis*, the measles virus and hantavirus. The major source of such infections in the laboratory is by procedures that cause aerosolization of the organisms. A particular hazard is presented by those agents that can withstand drying, such as *Coccidioides immitis*, as aerosols may settle, dry out and retain the potential to cause infection. Aerosol containment equipment and devices are essential to prevent the spread of infectious aerosols in the laboratory.

#### 5. Fomites

Fomites are objects that can be contaminated and then spread infectious agents such as doorknobs, elevator buttons, pens and pencils and mobile phones. Individuals can then unknowingly infect themselves via the transmission of organisms from fomites to the hands and then to the mouth or mucus membranes of the eyes or nose. Aerosols and droplets from spills can settle on laboratory furniture, apparatus, etc. can contaminate fomites. The telephone is a fomite as it can easily become contaminated.



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#### C. RISK GROUPS AND BIOSAFETY CONTAINMENT LEVELS

#### 1. Biological Risk Groups

Microorganisms are classified according to degree of risk in terms of infectivity, pathogenicity and the availability of preventive measures and effective treatments for the disease. The NIH Guidelines have established a classification and assigned human etiological agents into four risk groups based on hazard. The risk groups correlate with, but do not always equate to, biosafety levels. A risk assessment will determine the degree of correlation between an agent's risk group classification and biosafety level. The NIH Guidelines, Section II provides additional information on the differences and relatedness of risk groups and biosafety levels. There is no research with Risk Group 4 agents at the UW.

**Table 3-1: Risk Groups** 

Risk Group (RG)	Description	Examples
Risk Group 1 (RG1)	Agents that are not associated with disease in healthy humans	<ul> <li>E. coli K12 cloning strains</li> <li>Bacillus subtilis</li> <li>Canine hepatitis virus</li> </ul>
Risk Group 2 (RG2)	Agents that are associated with human disease which is rarely serious or for which preventative or therapeutic interventions are <i>often</i> available	<ul> <li>Salmonella typhimurium</li> <li>Pseudomonas aeruginosa</li> <li>Pathogenic E. coli</li> <li>Herpes simplex virus</li> </ul>
Risk Group 3 (RG3)	Agents that are associated with serious or lethal human disease for which preventative or therapeutic interventions may be available (high individual risk but low community risk)	<ul> <li>Yersinia pestis</li> <li>Francisella tularensis</li> <li>Hantavirus</li> </ul>
Risk Group 4 (RG4)	Agents that are likely to cause serious or lethal human disease for which preventative or therapeutic interventions are <i>not usually</i> available (high individual risk and high community risk)	<ul><li>Ebola virus</li><li>Marburg virus</li><li>Lassa virus</li></ul>



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#### 2. Biosafety Containment Levels

Biosafety is dependent on three elements: standard microbiological laboratory practices and techniques, safety equipment and facility design. Combinations of these three elements are used to describe the four biosafety levels. Additional information on biosafety levels and biological agent and toxins is also available in the CDC/NIH BMBL. There is no research requiring BSL-4 containment at UW. For more details regarding specific facility design elements for BSL-1, BSL-2, and BSL-3 laboratories, see Section 4 on facility requirements.

**Table 3-2: Biosafety Levels** 

Biosafety Level (BSL)	Description
Biosafety Level 1 (BSL-1)	<ul> <li>Suitable for work involving well-characterized agents not known to cause disease consistently in immunocompetent adult humans</li> <li>Agents present minimal potential hazards to laboratory personnel and the environment</li> </ul>
Biosafety Level 2 (BSL-2)	<ul> <li>Builds upon BSL-1</li> <li>Suitable for work involving agents that post moderate hazards to personnel and the environment</li> </ul>
Biosafety Level 3 (BSL-3)	<ul> <li>Builds upon BSL-2</li> <li>Applicable to facilities where work is performed with indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure</li> </ul>
Biosafety Level 4 (BSL-4)	<ul> <li>Builds upon BSL-3</li> <li>Required for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted infections and life-threatening disease that is frequently fatal and for which there are no vaccines or treatments</li> <li>Required for related agents with unknown risk or route of transmission</li> </ul>

## D. LARGE-SCALE CULTURE (>10 LITERS)

Large-scale culture (>10 L) presents unique challenges and hazards. The appropriate biosafety level for large-scale culture will be decided by the UW IBC and EH&S. The *NIH Guidelines* and CDC's BMBL both outline considerations and best practices for large-scale cultures.



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#### E. USE OF BIOLOGICAL TOXINS

A fundamental objective of a biosafety program includes the containment of potentially hazardous biological toxins. Biological toxins or biotoxins are poisonous substances produced by certain microorganisms, animals and plants, but they do not replicate and are therefore not considered infectious. However, because biotoxins may be extremely toxic in very small quantities, manage them as hazardous chemicals. A biosafety level is not necessarily assigned for toxin work.

Review and implement the safety guidelines detailed in EH&S's <u>Biological Toxin Safe Work Practices</u>. Labs working with biotoxins need a specific SOP for each toxin and documented training for personnel handling the toxin.

Select toxins are those regulated by the Federal Select Agent Program and may require additional safety and security requirements including registration with EH&S and the CDC. See <u>Select Toxins and Due Diligence</u> for more information.



## SECTION 4 – PROCEDURES FOR BIOHAZARD CONTROL

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#### A. FACILITY REQUIREMENTS

#### 1. BSL-1 Laboratory Facilities

- a. Laboratories have doors to control access.
- b. Laboratories have a sink for hand washing. The sink may be manual, hands-free, or automatically operated and ideally located near the exit door.
- c. The laboratory is designed so that it can be easily cleaned. Carpets and rugs are not permitted in the laboratory.
- d. Laboratory furniture are capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning.
- e. Bench tops are impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
- f. Chairs used in the laboratory work are covered with a non-porous material that can be easily cleaned and decontaminated with appropriate decontaminant. Fabric chairs are not allowed.
- g. Laboratories with windows that open to the exterior are fitted with screens.
- h. An eyewash station is readily available (within 50 feet of workspace and through no more than one door).
- i. Lighting is adequate for activities.

#### 2. BSL-2 Laboratory Facilities (in addition to BSL-1 requirements stated above)

- a. Planning of new facilities should consider ventilation systems that provide an inward flow of air without recirculation to spaces outside of the laboratory. See the <u>Laboratory Safety Design Guide</u> for specifications.
- b. Laboratory windows that open to the exterior are not recommended. However, if a laboratory does have windows that open to the exterior, they are fitted with screens.



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- c. Biological Safety Cabinets (BSCs) are installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. BSCs should be located away from doors, windows that can be opened, heavily traveled laboratory areas, and other possible sources of airflow disruptions.
- d. Vacuum lines are protected with liquid disinfectant traps and in-line HEPA filters. Replace HEPA filters at least annually or if visibly contaminated.
- e. HEPA-filtered exhaust air from a Class II BSC can be safely recirculated back into the laboratory environment if the cabinet is tested and certified at least annually and operated according to manufacturer's recommendations. BSCs can also be connected to the laboratory exhaust system either by a thimble (canopy) connection or by exhausting to the outside directly through a hard connection. Proper BSC performance and air system operation must be verified at least annually.

# 3. BSL-2 with BSL-3 practices Laboratory Facilities (in addition to BSL-2 requirements stated above)

- a. Laboratory doors are lockable to control access. Laboratory access is restricted to trained personnel.
- b. A dedicated entry area is used for donning and doffing personal protective equipment (PPE).
- c. Mechanical ventilation system provides inward flow of air without recirculation to spaces outside of the laboratory.
- d. All windows are sealed.

# 4. BSL-3 Laboratory Facilities (in addition to BSL-2 with BSL-3 practices requirements stated above)

- a. Laboratory doors are self-closing and the outside door is locked at all times. The laboratory is separated from areas that are open to unrestricted traffic flow within the building. Laboratory access is restricted. Access to the laboratory is through two self-closing doors. A clothing change room (anteroom) may be included in the passageway between the two self-closing doors.
- b. Hands-free or automatically operated sinks for hand washing are installed near exit door and in each laboratory.
- c. Walls and ceiling surfaces are sealed and have a smooth finish.
- d. Floors are slip resistant, impervious to liquids, and resistant to chemicals.
- e. A ducted air ventilation system provides directional airflow by drawing air into the laboratory from clean areas toward potentially contaminated areas. The laboratory is designed such that, under failure conditions, the airflow is not reversed. Laboratory personnel are able to verify directional airflow with a visual monitoring device. Laboratory exhaust air does not recirculate to any other area of the building.
- f. At the UW, the laboratory building exhaust air is HEPA-filtered and dispersed away from occupied areas and from building air intake locations. The filters and the housing are certified at least annually.



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- g. A method for decontaminating all lab wastes is available in the facility (e.g., autoclave, chemical disinfection, incineration, or other validated method).
- h. At the UW, the BSL-3 facility design, operational parameters, and procedures are verified and documented by an outside contractor prior to operation. Facilities are verified that they meet the intent of the current edition of the CDC/NIH <u>BMBL</u> and documented at least annually.

#### **B. PERSONAL PROTECTIVE EQUIPMENT (PPE)**

The purpose of personal protective equipment (PPE) is to prevent biohazards from reaching clothing, undergarments, skin, eyes, mouth, or other mucous membranes. PPE is considered the last line of defense for protection and when possible should not be only form of exposure control. PPE should be used in combination with engineering controls, such as biological safety cabinets, and work practice controls, such as minimizing aerosol generation and using good microbiological practices.

The minimum requirements for personal protective equipment (PPE) are specified below. Laboratory-specific rules concerning personal and protective clothing must be determined by the PI, documented in the lab, and enforced by the PI. Use the <u>Laboratory PPE Hazard Assessment Guide</u>. Shoes should fully cover the feet to protect against spills; open-toed shoes or sandals are not permitted in laboratories. Clothing should fully cover the legs. Hair, beards, personal clothing, and shoes can effectively disseminate infection. (See fomites in Section 4.A.4). See the UW Laboratory Safety Manual Section 5.B.2. for more information on appropriate laboratory apparel.

Do not wear gloves and other PPE outside of the laboratory.

#### 1. Laboratory Coats

Launder reusable laboratory coats on a regular basis and never take laboratory coats home.

- a. **BSL-1 laboratories:** Wear laboratory coats for general biological work in a BSL-1 laboratory when handling biohazardous agents, including recDNA. Laboratory coats are also required when working with hazardous chemicals, radioisotopes, etc.
- b. **BSL-2 laboratories:** Wear dedicated laboratory coats, gowns, or smocks while working in the BSL-2 laboratory area. Remove protective clothing before moving from the BSL-2 laboratory area to a non-BSL-2 laboratory area (e.g., BSL-1 laboratory, hallway, cafeteria, library, administrative office) and leave it in the laboratory.
- c. **BSL-2 with BSL-3 practices and BSL-3 practices laboratories:** All the rules for BSL-2 laboratory apply. In addition, wear laboratory clothing that protects street clothing (solid front or wrap-around gowns, scrub suits or coveralls) in the laboratory. Do not wear laboratory clothing outside the laboratory; autoclave clothing before laundering or disposal. Tight fitting cuffs on laboratory clothing or sleeve protectors are useful.

#### 2. Gloves

Glove selection is based on an appropriate risk assessment. In laboratory settings, the most common gloves are latex and nitrile, and both are appropriate for protection against biohazardous agents but do not provide protection from punctures caused by sharp items or broken glass. However, latex is associated with allergies; provide non-latex glove options if allergies exist.



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If work involves the use of chemicals with biohazardous agents, select gloves according to recommendations in the <u>Laboratory Safety Manual</u> and refer to the associated Material Safety Data Sheet (MSDS). Many chemicals destroy the integrity of latex gloves (e.g., do not use 70% ethanol with latex gloves).

- Always visually check gloves for defects before using (e.g., look at gloved hands).
- Change gloves when contaminated, torn, or punctured. Take care not to touch your skin with the outer surface of the gloves when removing them. Wash hands immediately after gloves are removed and before leaving the laboratory.
- Remove gloves prior to handling non-contaminated items such as doorknobs or telephones. Do not wear gloves outside the laboratory area.
- Do not wash or disinfect and then reuse disposable gloves. Detergents may cause enhanced penetration of liquids through undetected holes, and disinfectants may cause deterioration.
- Used gloves must be treated as biohazardous waste and decontaminated prior to disposal.
- Use double glove practices in BSL-2 laboratories following BSL-3 practices and BSL-3 laboratories.

#### 3. Eye and Face Protection

Eye and face protection is required for activities in which there is a potential for splash/splatter of biohazardous agents onto the mucous membranes of the mouth, nose, and eyes.

- **a. Eye protection –** Use goggles, safety glasses with side shields, surgical masks, face shields, or other splatter guards for anticipated splashes or splatters of biohazards when agents must be handled outside the BSC or containment device. Dispose of eye protection with other biohazardous waste or decontaminate before reuse. Eye protection is required for persons who wear contact lenses in laboratories.
- b. Face Shields Full-face shields made of lightweight transparent plastic are the preferred means of facial protection. They can offer excellent protection of the entire face and neck region and can easily be decontaminated. Face shields can also be used with a mask or respirator. If face shields are not used, use a combination of face mask and eye protection whenever splashes, spray, or splatter of biohazardous agents may be generated and where eyes, nose, or mouth contamination can be reasonably anticipated.
- **c. Surgical Masks with liquid barriers –** Surgical masks protect the mucous membranes in the mouth and nose from splashes or splatters but do not protect against aerosols. Either soft or preformed masks are effective.
- d. Goggles/Safety Glasses with side shields Ordinary prescription glasses do not provide adequate eye protection. Use plastic safety glasses with side shields that fit over regular glasses or goggles. If there is a substantial hazard for splattering, use safety goggles with a seal. Goggles that seal around the eyes are preferred over safety glasses with side shields.



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- **e. Respirators** A respirator protects the nose, mouth, and respiratory tract from aerosols. Based on EH&S risk assessment, a respirator may be needed if aerosols are generated outside of appropriate containment.
- f. Handling Infected Animals Eye, face, and respiratory protection should be used in rooms containing infected animals as determined by the risk assessment. Wear molded surgical masks or respirators in ABSL-3 rooms containing infected animals. Wear gloves when handling infected animals and when there is potential skin contact with biohazardous agents.

#### g. Alternatives of facial barrier protection:

- Use a BSC: Perform the manipulations in a Class II BSC.
- Use a splash shield: A clear plastic shield that can be placed on the bench top
  provides an effective barrier for potential splashes/splatters. It is not effective for
  manipulations that create aerosols; perform such manipulations in a BSC.

#### 4. Respiratory Protection

Respiratory protection should be included as part of the risk assessment for work at BSL-2 and higher. If respiratory protection is deemed necessary, contact EH&S at <a href="https://www.edu">uwresp@uw.edu</a> for an assessment. If you wear a respirator at UW, you must use it according to the <a href="https://www.edu">UW Respiratory</a> <a href="https://www.edu">Protection Program</a>.

#### C. GOOD LABORATORY PRACTICES AND TECHNIQUES

The following practices and techniques apply at BSL-1 to BSL-3 unless otherwise specified.

#### 1. Technical Proficiency

Laboratory personnel must be aware of the potential hazards and must be trained and proficient in the necessary practices and techniques required for safe handling of biohazardous agents. Laboratory personnel must have documented training in handling biohazardous agents. The PI is responsible for providing or arranging for appropriate training for all personnel working in their laboratory.

Laboratory personnel working in BSL-2 laboratories with BSL-3 practices or in BSL-3 laboratories must have documented training on the laboratory-specific biosafety manual and practical training with the PI. All required EH&S safety classes (e.g., biosafety training, bloodborne pathogens training) must be current.

#### 2. Hazard Awareness Training

#### a. Biosafety Training

Completion of the EH&S online Biosafety training is required every three years for PIs if their research includes the use of biohazardous agents. It is also required for students, fellows, laboratory managers, research staff, and all other staff who have the potential for exposure to recDNA and other biohazardous agents. This training is required before initiating research with biohazardous agents, including recDNA, and every three years thereafter.



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#### b. Bloodborne Pathogens (BBP) Training

Staff with reasonably anticipated potential for exposure to human blood, human source material, all human cell lines, and other potentially infectious materials must take the <a href="EH&S">EH&S</a> online bloodborne pathogens (BBP) training. The training is required initially and every year thereafter.

#### c. Visitor Training

All persons entering the laboratory or facility are advised of potential hazards, instructed on the appropriate safeguards, and read and follow instructions on practices and procedures.

#### 3. Prohibited Activities

- a. Eating, drinking, handling contact lenses, applying cosmetics, chewing gum, and storing food for human consumption is not allowed in the laboratory. Smoking is not permitted in any University building. Food shall not be stored in laboratory refrigerators or prepared/consumed with laboratory glassware or utensils. Food may be stored in cabinets and refrigerators marked for "FOOD ONLY." These must be located outside the laboratory work area and physically separated by a door from the main laboratory.
- b. Mouth pipetting is prohibited in research laboratories; only mechanical pipetting devices can be used.
- c. There are restrictions on storage of laboratory equipment in public corridors. Information on storage in hallways and stairwells is available <u>online</u>.
- d. Animals and plants not associated with the work being performed are not permitted in the laboratory.
- e. Personal protective equipment (e.g., lab coats, gloves) cannot be worn in public hallways.
- f. Biohazardous agents (including biohazardous waste) cannot be transported in public corridors without a secondary container.

#### 4. Restrict Traffic in Laboratories

- **a. BSL-1 laboratories:** Doors to BSL-1 laboratories can remain open, even during active research, but care should be taken to limit casual access by the general public.
- b. BSL-2 laboratories: When biohazardous agents are in use, the door to a BSL-2 laboratory should remain closed with the BSL-2 Biohazard Warning Sign displayed. The door is locked when the laboratory is unoccupied.
- c. BSL-2 with BSL-3 practices laboratories: When biohazardous agents are in use, the door to a BSL-2 with BSL-3 practices laboratory should remain closed with the BSL-2 with BSL-3 practices Biohazard Warning Sign displayed. The door is locked when the laboratory is unoccupied. Laboratory access is restricted to trained personnel.
- **d. BSL-3 laboratories:** Entry to BSL-3 laboratories is restricted by a double set of doors. The outer door of the BSL-3 laboratory is locked at all times with the BSL-3 Biohazard Warning Sign permanently affixed to the door.

The <u>Biohazard Warning Door Sign</u> must include the assigned biosafety level (BSL), name of the biological agent(s) in use, the name and phone number of the PI, the name and phone number of other responsible personnel, specific entry/exit and PPE requirements, and any occupational



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health requirements. See Appendix B for additional information on the use of the Biohazard Warning Sign.

## 5. Handwashing

Laboratory workers must wash their hands after handling biohazardous agents or animals, after removing gloves, and before leaving the laboratory area.

## 6. Post Spill and Exposure Response Procedures

Post appropriate spill response and exposure response procedures in all locations where biohazards are used including animal research spaces. Post the current versions of the EH&S <u>Spill Response Poster</u> and <u>Exposure Response Poster</u>, and review the procedures with lab personnel.

## 7. Long Hair

Restrain or tie back long hair so that it cannot contact hands, specimens, containers or equipment.

## 8. Biosafety Manual and Laboratory-Specific Biosafety Manual

BSL-1 and BSL-2 laboratories must have access to a current copy of the UW Biosafety Manual by a prominently displayed icon on a computer desktop or a hard copy. BSL-2 laboratories with BSL-3 practices and BSL-3 laboratories must also have a laboratory-specific biosafety manual with written standardized safety procedures that have been reviewed by an EH&S BSO.

## 9. Good Housekeeping

Keep work areas free of clutter and cleaned regularly. Wet mopping is preferred over dry sweeping or the use of vacuums, which create aerosols.

Work surfaces are decontaminated once a day and after any spill of potentially viable material. Decontamination is covered in Section 4.F and spill cleanup is in Section 6.A of this manual.

## 10. Inventory Control

Laboratories should have a process for controlling inventory of infectious agents. Document and label all microorganisms stored in the lab. Properly decontaminate and dispose of any stocks or cultures that are not needed. If any select agents or select toxins are discovered, contact EH&S immediately for assistance.

### 11. Pest Control

Pest control is best accomplished by maintaining good housekeeping. A good sanitation program is fundamental to the control of vermin and includes a program of storage, collection, and disposal of solid wastes. Caulking of cracks and crevices in the room is also important.

The UW employs a licensed pest control operator to control vermin in strict accordance with applicable laws and regulations. Contact EH&S at <a href="mailto:phdept@uw.edu">phdept@uw.edu</a> or 206-616-1623if vermin problems are suspected so that a <a href="mailto:pest">pest control program</a> can be implemented.

Decontaminate all biohazardous liquid or solid wastes before disposal. This includes waste from research with all forms of recDNA. Do not fill sharps containers to more than two-thirds full. Decontamination is covered in Section 4.F. and waste disposal is covered in Section 4.G.



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#### 12. Minimization of Aerosols

Perform all procedures carefully to minimize the creation of aerosols. Use BSCs or other physical containment devices whenever aerosol-generating procedures are conducted (e.g., pipetting, centrifuging, grinding, blending, shaking, mixing, sonicating, or opening containers of biohazardous agents).

In BSL-2 laboratories with BSL-3 practices and BSL-3 laboratories, conduct open manipulations of all biohazardous agents inside a BSC or other physical containment device.

## D. LABORATORY EQUIPMENT

This section describes the different types and proper use of laboratory safety equipment. Equipment must be marked with the biohazard symbol or the word biohazard where it is necessary to alert personnel of the potential for exposure. Refer to Appendix B for additional labeling information.

Equipment which may be contaminated with blood or potentially infectious materials must be decontaminated prior to servicing. When a portion of the equipment cannot be decontaminated, the equipment must be labeled with the biohazard label and a sign stating which portion of the equipment remains contaminated. This information must be conveyed to all repair workers and servicing representatives and/or the manufacturer as necessary prior to handling, servicing, or shipping so that appropriate precautions can be taken.

Equipment being repaired, surplused, or disposed of must be decontaminated. A <u>Notice of Laboratory Equipment Decontamination</u> (Form UoW 1803) must be completed to certify decontamination.

#### 1. Biological Safety Cabinets (BSC)

The <u>BSC</u> is designed to reduce the potential escape of research material into the worker's environment and to remove contaminants from the research work zone.

The following types of Class II BSCs provide a clean work zone (product protection), aerosol protection for the operator (personnel protection), and environmental protection through use of a HEPA filter. HEPA filters are effective at trapping particulates and thus infectious agents. They do not capture volatile chemicals or gases. Only Type A2 exhausted or Types B1 and B2 BSCs exhausting to the outside should be used when working with volatile toxic chemicals. In any case, amounts of these chemicals must be limited.

Other equipment such as horizontal laminar flow units, vertical laminar flow units, and non-ventilated tissue culture boxes are not biosafety cabinets. They provide only limited product protection and do not provide any personnel protection. If laminar flow units are present in the laboratory, they must be labeled "NOT for Use with Pathogenic Organisms."

#### a. Types of Biological Safety Cabinets

- Class II Biosafety Cabinets (Equipment to protect the worker, product, and environment)
  - i. Class II, Type A1 BSCs are suitable for work with low to moderate risk biological agents requiring BSL-1, BSL-2, or BSL-3 containment in the absence of volatile toxic chemicals and volatile radionuclides. The buildup of chemical



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- vapors in the cabinet (by recirculated air) and in the laboratory (from exhaust air) could create health and safety hazards.
- **ii. Class II, Type A2 BSCs** (formerly designated Type B-3) are suitable for work with low to moderate risk biological agents requiring BSL-1, BSL-2, or BSL-3 containment. Minute quantities of volatile toxic chemicals or volatile radionuclides can be used in a Type A2 cabinet only if the cabinet exhausts to the outside via a properly functioning canopy connection.
- **iii. Class II, Type B1 BSCs** are suitable for work with biological agents requiring BSL-1, BSL-2, or BSL-3 containment. They may also be used with biological agents treated with toxic chemicals and trace amounts of radionuclides required as an adjunct to microbiological studies if work is done in the direct exhausted portion of the cabinet or if the chemicals or radionuclides will not interfere with work when recirculated in the downflow.
- **iv. Class II, Type B2 BSCs** are suitable for work with biological agents requiring BSL-1, BSL-2, or BSL-3 containment. They may also be used with biological agents treated with toxic chemicals and radionuclides required as an adjunct to microbiological studies. This type of cabinet is sometimes referred to as a "Total Exhaust Cabinet."
- v. Class II, Type C1 BSCs are capable of being configured in the recirculating Type A mode for standard microbiological work or may be connected to the building exhaust to function in the Type B mode for handling biological material with hazardous chemical vapors or radionuclides.
- 2) Class I Biosafety Cabinets (Equipment that can be used to provide limited personnel protection but no product protection)
  - i. A **Class I BSC** is similar to a fume hood in its basic design and personnel protection capabilities. This cabinet can be used for work at BSL-2 containment when minimal personnel protection and no product protection is required. The cabinet's exhaust air is filtered through a HEPA filter. The filter provides a significant degree of environmental protection, which a fume hood does not offer.

#### b. BSC Certification

Equipment must be decontaminated prior to performance of maintenance work, repair, testing, moving, changing filters, changing work programs, and after gross spills. Decontamination can be done using paraformaldehyde. Contact EH&S at 206-543-9510 for information on decontamination.

The methods and requirements for testing BSCs vary depending upon the design of the cabinet and its intended use. While structural certification of the BSC is made by the manufacturer prior to shipment, stress during shipment can alter the integrity and efficiency of the BSC.

All research materials must be removed from the BSC prior to testing and certification. Plan and schedule in advance as the BSC cannot be used until certification is complete.



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The University's IBC requires that all BSCs be tested and certified prior to initial use, relocation, after HEPA filters are changed, and at least annually.

The testing and certification process includes:

- A leak test to assure that the airflow plenums are gas tight in certain installations.
- A HEPA filter leak test to assure that the filter, the filter frame, and filter gaskets are all properly in place and free from leaks. A properly tested HEPA filter will provide a minimum efficiency of 99.99% on particles 0.3 microns in diameter and larger.
- Measurement of airflow to assure that velocity is uniform and unidirectional.
- Measurement and balance of intake and exhaust air.

Users must receive training prior to use of BSCs. This training is the responsibility of the PI.

## c. Basic Guidelines for Working in a BSC

- Never place anything over the intake or rear exhaust grill. Keep equipment at least four inches inside the cabinet window and perform all transfer operations of viable material as deeply into the BSC as possible.
- ii. Do not overload BSC with equipment and other items. Only bring in items needed for work.
- iii. Plan in advance to have all required equipment inside the BSC. Good laboratory technique minimizes arm movements through the air barrier until the procedure is completed.
- iv. During manipulations inside the BSC, segregate contaminated and clean items. Keep clean items out of the work area, and place discard containers to the rear of the BSC.
- v. Avoid entrance and exit from the workroom. Foot traffic can cause disruptive drafts that allow microorganisms to escape through the air barrier of the BSC.
- vi. Equipment should be kept as parallel as possible to the downflow of the airstream. Large pieces of equipment can disrupt the airflow. Contact EH&S for an assessment for use of large or bulky equipment.
- vii. To purge airborne contaminants from the work area, allow the BSC to run following completion of work. The BSC can be turned off after 20 minutes but it is recommended that it be left on continuously.
- viii. Decontaminate the BSC after use (see Section 4.F). Choose a disinfectant that does not corrode the stainless steel surface, or follow disinfection with an ethanol or water wipe to remove corrosive chemicals.
- ix. Do not use an open flame Bunsen burner inside a BSC. If required, a touch-a-matic burner or infrared loop sterilizer should be used. An open flame Bunsen burner disrupts the unidirectional air stream. The flame could damage the filter or set fire to the BSC when the BSC is turned off.
- x. Do not use the BSC for storage when not in use.



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## 2. Blenders, Ultrasonic Disintegrators, Grinders, and Mortar and Pestle

All of these devices release considerable aerosols during their operation. For maximum protection to the operator during the blending of biohazards, the following practices should be observed:

- a. Operate blending, cell disruption, and grinding equipment in a BSC.
- b. Use a heat-sealed flexible plastic film enclosure for a grinder or blender. The grinder or blender must be opened in a BSC.

## 3. Automated Equipment

Clinical or other laboratory personnel handling human blood, non-human primate blood, and other biohazards should be aware of aerosols produced by the micro-hematocrit centrifuge, the autoanalyzer, and the microtonometer.

## 4. Water Baths and Incubators

After use, decontaminate water baths and incubators with an appropriate decontaminant (see Section 4.F).

Maintenance service on water baths and incubators that appear to be improperly used and/or contaminated may be denied. It is not the responsibility of maintenance personnel to clean up after laboratory personnel.

## 5. Refrigerators, Deep Freezers and Dry Ice Chests

Deep freezers, liquid nitrogen, dry ice chests, and refrigerators should be checked and cleaned out periodically to remove any broken ampoules, tubes, etc., containing biohazards.

Containers must be stored in proper order and sequence and properly labeled to preclude withdrawal of the wrong ampoules or tubes. Use of gloves and respiratory protection during cleaning of refrigerators, deep freeze or dry ice chests is recommended. All materials that are stored should be properly labeled with the scientific name, the date stored, and the name of the individual storing the material.

Flammable solutions that require 4 degree storage conditions must be stored in a refrigerator approved for flammable storage. Contact <u>EH&S Fire and Life Safety</u> for more information.

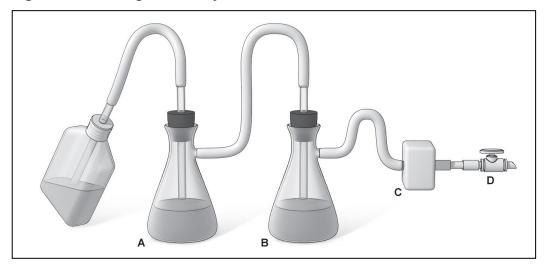
#### 6. Laboratory Vacuum Lines

Appropriate in-line safety reservoirs and filters ensure that laboratory vacuum lines do not become contaminated with biohazardous agents. Aspirator bottles or suction flasks (Figure 1) should be connected to an overflow collection flask (Figure 1, B) containing appropriate disinfectant and to an in-line HEPA filter (0.3 micron pore size recommended) or equivalent filter (Figure 1, C). This combination will provide protection to the central building vacuum system or vacuum pump, as well as to the personnel who service this equipment. In-line HEPA filters should be replaced at least annually or if visibly contaminated. If glass flasks are used, they should be placed in leak-proof secondary containment in the event of a break or spill. Label aspirator bottles or flasks as "biohazard waste" and treat with bleach so that a final concentration of 10% bleach is in contact with the contents for at least 30 minutes before disposal.



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**Figure 1: Protecting Laboratory Vacuum Line** 



One method to protect a house vacuum system during aspiration of infectious fluids. The left suction flask (A) is used to collect the contaminated fluids into a suitable decontamination solution; the right flask (B) serves as a fluid overflow collection vessel. An in-line HEPA filter (C) is used to protect the vacuum system (D) from aerosolized microorganisms.

## 7. Microtomes and Cryostats

The microtome and the cryostat are used for cutting thin sections of fixed and unfixed tissue. The use of microtomes and cryostats in the laboratory presents a laceration hazard in addition to generating potentially infectious aerosols. Unfixed tissues should be considered capable of causing infection and should be treated with care. Employees who handle or could be exposed to tissue of human origin must be enrolled in the UW BBP Program (Appendix A).

Observe the following procedures when using microtomes/cryostats:

- a. Always keep hands away from blades.
- b. Position the sample first and then put in the blade with the blade edge positioned away from hands.
- c. Use engineering controls like forceps, tweezers, dissecting probes, and small brushes to retrieve samples, change blades, dislodge blocks, or clean equipment.
- d. Use protectors/guards for knife-edges that may extend beyond the microtome knife holder.
- e. Wear appropriate personal protective equipment (PPE) such as gloves, lab coat or gown, mask, and safety glasses or goggles. Consider the use of surgical grade Kevlar gloves when using a cryostat to provide additional protection from cuts and scrapes.
- f. Do not leave motorized microtomes running unattended.
- g. Discard and handle trimmings and sections of tissue as biohazardous waste.
- h. Do not move or transport a microtome with the knife in position.
- i. Always lock the chuck rotating mechanism (wheel) to immobilize the block when not actively cutting tissue and before insertion or removal of the blade.



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- j. Never walk away from an exposed blade.
- k. At the end of each session with the microtome or cryostat, either dispose of the blade immediately in a sharps container or secure reusable blades in a container.

#### E. LABORATORY PROCEDURES

This section describes proper techniques used when working with biohazardous agents (e.g., pipetting; working outside a BSC; using needles; opening culture plates, test tubes, bottles, or ampoules; handling laboratory glassware; cell sorting; and centrifugation).

## 1. Pipetting

Delivery with the tip of the pipette resting against the container allows the fluid to flow down the surface and minimizes aerosols.

Allowing a droplet to fall from the tip of a pipette, intentionally or accidentally, results in aerosol production, the extent of which depends on the height of the fall and the surface upon which the droplet lands. The following procedures should be followed for pipetting:

- a. Mouth pipetting is strictly prohibited. Mechanical pipetting aids must be used.
- b. Infectious mixtures should not be prepared by bubbling air through the liquid with the pipette.
- c. Infectious materials should not be forcibly discharged from pipettes (e.g., the last drop forcefully removed).
- d. A towel wetted with disinfectant or a soft absorbent pad covering the immediate work surface is most useful in absorbing droplets and small spills.

## 2. Using Needles and Other Sharps

Sharps are items that are used to cut or puncture skin or body parts, including needles, scalpels and lancets. Other sharp items can still cause injuries although they do not fit the regulatory definition of sharps, such as broken glass, glass septum vials, glass pipets, razor blades, and the sharps teeth and nails of research animals. Safety precautions are necessary to prevent injury and exposure.

Identify sharps devices to be used in laboratory procedures. When possible, substitute a non-sharp alternative such as a blunt needle or plastic pipet, or consider using a safe sharps device. If a sharp must be used, training and practice are essential to prevent injury. Avoid factors and conditions that can lead to a sharps injury, such as hurrying or rushing or working when you are tired or not feeling well. Keep your work area organized and uncrowded so that sharps items are always visible. More information on sharps safety is available in our <a href="Sharps Safety webpage">Sharps Safety webpage</a> and <a href="Work Safety with Sharps Focus Sheet">Work Safety with Sharps Focus Sheet</a>.

Avoid recapping needles. If a needle must be recapped, using a needle holder to do so. Never leave an uncapped needle exposed in the work area. Store reusable sharp items in a labeled storage container such as a bucket or tray. Use a magnet to contain reusable metal sharp items like razor blades. Promptly place all sharps waste into a red sharps container. The container must be decontaminated by autoclaving before discarding. Additional information on waste disposal is found in Section 4.G.



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When working with needles:

- a. Use extreme caution to avoid accidental injection and the generation of aerosols during use and disposal.
- b. Use needles only for injection and aspiration of fluid from laboratory animals and diaphragm bottles.
- c. Do not use a syringe and needle as a substitute for a pipette when making dilutions of fluids. Syringe-type pipettes with blunt ended delivery are permissible.
- d. Use needle locking syringes or disposable syringe-needle units in which the needle is an integral part of the syringe.
- e. Prior to beginning an animal inoculation, be sure the animal is properly restrained. Swab the site of the injection with a suitable disinfectant. Inoculate the animal with a hand behind the needle to avoid punctures. Swab the injection site again with a suitable disinfectant.
- f. Following use, needles should not be bent, sheared, or removed from the syringe. If you need to change a needle after drawing up a dose, use a tool to remove.

See Sharps and Laboratory Glass for disposal information.

## 3. Centrifugation

Accidents resulting from the improper use of centrifuges are rare; however, if accidents do occur, aerosols can be created and increase the possibility of causing lab-acquired infections. Even a well-functioning centrifuge is capable of producing biohazardous aerosols. Aerosols can be avoided by observing sound laboratory practices and using appropriate centrifuge safety equipment as described below. Properly maintain centrifuges according to manufacturer's instructions to reduce the risk of mechanical failures.

For centrifugation of biohazardous agents:

- a. Use a centrifuge with an aerosol containment device such as sealed safety cups or a sealed rotor. Remove the aerosol containment device and open inside of a BSC;
- b. If a centrifuge with the above controls is not available, place and operate the centrifuge within a BSC.
- c. If neither option is possible, contact an EH&S BSO for assistance with alternate controls or practices at <a href="mailto:ehsbio@uw.edu">ehsbio@uw.edu</a> or 206-221-7770.

The greatest hazard associated with centrifuging biohazards is created when a centrifuge tube breaks. Do not use glass centrifuge tubes for biohazardous materials. Instead, use plastic tubes and bottles because they resist breakage. However, plastic materials are not indestructible. Be aware of signs of deterioration in plastic such as crazing, cracking or spotting. Check to see if plastics are compatible with chemical components to be centrifuged. If not, choose a different container.

Do not fill tubes to the point that the rim of the closure becomes wet with culture. Pay special attention when filling tubes to be placed in a fixed angle centrifuge. Do not fill tubes so high that the liquid can spill out when the tube is at an angle.



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Never use aluminum foil or cotton plugs to cap centrifuge tubes containing biohazards because they can detach or rupture. Instead, use tight-fitting tabbed or hinged caps made of plastic or rubber, screw caps, or other tight-fitting plastic or metal closures. Screw caps, or other tight-fitting skirted caps that fit outside the rim of the centrifuge tube are safer to use than plug-in closures. Some fluid usually collects between a plug-in closure and the rim of the tube. Even screw-capped tubes and bottles are not without risk; if the rim is soiled and seals imperfectly, some fluid will escape down the outside of the tubes.

Proper balancing of the centrifuge is important. Care must be taken to ensure that matched sets of safety devices and adapters do not become mixed. If the components are not inscribed with their weights by the manufacturer, label to avoid confusion.

Properly maintain centrifuges according to manufacturer's instructions to reduce the risk of mechanical failures. Follow the manufacturers' recommendations for cleaning and disinfection of tubes, aerosol containment devices, rotors, and other centrifuge components. Inspect all components, including the sealing gaskets, periodically for wear. When problems are noted, the components must be replaced.

In the event of a centrifuge malfunction and/or spill that may create hazardous aerosols, vacate that room for at least 30 minutes to allow the aerosols to dissipate. Contaminated areas, broken glass, etc. should then be properly decontaminated and cleaned up promptly. The person using the centrifuge, along with the PI and/or laboratory manager, are responsible for ensuring that clean-up and decontamination is achieved. Maintenance service may be refused on centrifuges which appear to be improperly used and/or contaminated.

## 4. Resuspending Sediment of Centrifuged Material

Use a swirling, rotary motion rather than shaking to resuspend the sediment of packed biohazardous materials. This motion minimizes the amount of aerosol created. Perform these operations inside a BSC. If vigorous shaking is essential to suspend the material or achieve homogeneity, allow a few minutes to elapse before opening the container to allow the aerosol to settle. Shaking always contaminates the closure and creates the added hazard of liquid escaping and running down the outside of the container or dropping from the closure when it is removed.

## 5. Working Outside a BSC Using a Splash Guard and/or Additional PPE

In cases where the biohazardous agent is not transmitted via a route of inhalation (e.g., opening tubes containing blood or body fluids), it is permissible to work outside a BSC using a splash guard. A splash guard is an example of a barrier type engineering control that protects by providing a shield between the user and any activity that could cause an aerosol or splatter. An example of such a splash guard is a simple clear plastic panel formed to stand on its own and provide a barrier between the user and activities such as opening tubes that contain blood or other potentially infectious materials (OPIM). Additional PPE (e.g., safety goggles, glasses, face shield) may be required for splash protection when working with biohazardous materials outside a BSC.

## 6. Opening Culture Plates, Tubes, Bottles, and Ampoules

Aerosol formation is the primary concern when plugs or screw caps are removed from tubes and bottles. Slow and smooth manipulations will minimize aerosols. See Section 4.B.4.c Facial Protection for additional information.



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Opening ampoules is potentially hazardous since, after the seal is broken, the air rushes in causing the dry contents to be dispersed. A BSC should be used. The bottom of the ampoule should be held in several layers of lab wipes to protect the hands. Nick the neck of the ampoule with a file. A hot glass rod should be carefully applied to the mark. The glass will crack, allowing air to enter the ampoule and equalize the pressure. After a few seconds the ampoule should be wrapped in a few layers of lab wipes and broken along the crack.

An alternative method of opening an ampoule involves wearing gloves and other PPE, nicking the ampoule with a file, and wrapping the ampoule in disinfectant wetted cotton for breaking.

In both methods the ampoule neck and other waste is handled as biohazardous sharps waste. Additional information on Waste Disposal is found in Section 4.G.

## 7. Using Test Tubes and Other Laboratory Glassware

Tubes containing biohazards should be manipulated with extreme care. Studies have shown that simple procedures such as removing the tube cap or transferring an inoculant can create a potentially hazardous aerosol. Tubes and racks of tubes containing biohazards should be clearly marked with agent identification.

Safety test tube trays should be used in place of conventional test tube racks to minimize spillage from broken tubes. A safety test tube tray is one that has a solid bottom and sides that are deep enough to hold all liquids if a tube should break. Glassware breakage is a major risk for puncture infections. Use non-breakable containers when. Avoid unnecessary use of glass Pasteur pipettes. Whenever possible, use flexible plastic pipettes or other alternatives.

It is the responsibility of the PI and/or laboratory manager to assure that all glassware/plasticware is properly decontaminated prior to washing or disposal. See Section 4.F for additional information on decontamination and disposal

#### 8. Cell Sorting

Clinical or other laboratories handling human blood, non-human primate blood, recDNA, and other biohazardous agents should be aware of aerosols produced by the cell sorter. High-speed cell sorting can produce aerosols that may present a health hazard to workers. The <a href="International Society for the Advancement of Cytometry (ISAC)">International Society for the Advancement of Cytometry (ISAC)</a> has resources on biosafety as related to flow cytometry and cell sorting. To help ensure the safety of staff, the following additional safety measures are used:

- a. Engineering controls, that may include an Aerosol Management System (AMS) that rapidly evacuates and filters aerosolized particles from the cell sorter chamber.
- Safe practices, that may include additional PPE and training, are unique to each UW facility and must be followed as specified in the cell sorter core facility Manual of Standard Operating Procedures (SOPs).
- c. EH&S and IBC approval may be required prior to sorting specific cell types, (e.g., all human cells including human cell lines, cells containing recDNA, cells exposed to virus or bacteria). Contact EH&S ROS for more information at <a href="mailto:ehsbio@uw.edu">ehsbio@uw.edu</a> or 206 221-7770.



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## F. CONTROL OF BIOHAZARDS ASSOCIATED WITH LABORATORY ANIMALS

## 1. Responsibility

Procedures designed to prevent exposure to or transmission of biohazards from laboratory animals to human beings must be taken into account. Both naturally occurring diseases of laboratory animals transmissible to humans and experimentally induced disease, which may be harmful to humans, must be considered. The ultimate responsibility for reducing or eliminating such risks lies with the PI.

Programs for the safe handling and ultimate disposition of potentially contaminated animals and animal wastes must protect the health and well-being of the employee, maintain the integrity of the experimental program, and minimize the hazard to non-program personnel or animals in adjacent areas. Such programs are based on an understanding of the hazard potential involved in working with animals. Procedures, equipment, and facilities must be selected to minimize or eliminate such risks. A carefully conceived animal care program and properly designed animal facility are necessary to reduce biohazard exposure in animal facilities. Definitive procedures that encompass all potential exposure possibilities are beyond the scope of this document.

PIs are responsible for providing specific information to their personnel concerning the biohazardous agent involved (carcinogen, radioactive isotope, etc.), its host range, the ability of experimentally infected animals to infect non-exposed animals or to excrete the agent in urine or feces, special caging or animal isolation requirements, the need to autoclave isolation cages and their content prior to processing, and the selection and use of appropriate PPE.

#### 2. Animal Blood and Blood Products

This section describes how to work safely with non-human primate and animal (non-primate) blood, body fluids, tissues, and cell lines.

## a. Non-Human Primate Blood, Body Fluids, Tissues and Cell Lines

Investigators working with non-human primates or non-human primate blood, body fluids, tissues, and cell lines should be concerned about safe handling because of the extreme severity of some of the agents that primates can harbor without showing any clinical disease. Some of the agents that can result in fatal infections in humans are Macacine herpesvirus 1, Marburg virus, and *Shigella* spp. A significant proportion of monkeys have latent shigellosis, and about 65% of *Macaca* spp. have antibodies to Macacine herpesvirus 1.

In addition, in September 1992, the CDC reported that two laboratory workers seroconverted following occupational exposure to simian immunodeficiency virus (SIV), a lentivirus that causes acquired immunodeficiency syndrome (AIDS)-like illnesses in susceptible *Macaca* spp.

The same blood and body fluid precautions used for humans (Appendix A) must consistently observed with all specimens from non-human primates. All laboratory personnel must be familiar with these precautions prior to working with primate body fluids.

#### b. Animal (non-primate) Blood, Body Fluids and Tissue, and Cell Lines

Non-primates generally present a less immediate hazard potential than do primates. However, bats, dogs, cats, rabbits, rats, mice, etc. can carry microorganisms that are



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infectious to humans. In particular, animals acquired from unregulated sources must be considered a potential source of infection. For example, dogs and cats can carry rabies. Other infectious agents may be present without producing clinical illness in the animal. Generally, the same good laboratory practices used when working with primate source materials are followed when working with non-primate blood, body fluids, and tissue.

## 3. Animal Biosafety Levels and Vivarium Research Facilities

As a general principle, the biosafety level (facilities, practices, and operational requirements) recommended for working with biohazardous agents in vivo and in vitro are comparable. All facility requirements discussed for biosafety laboratories in Section 4.A.1 apply to research with animals as well. This includes posting spill clean-up procedures in all animal rooms at ABSL-1 and above.

The animal room can present unique problems. The activities of the animals themselves can present special hazards not found in standard microbiological research laboratories. Animals may generate aerosols, they may bite and scratch, and they may be infected with a zoonotic agent. All additional animal facility SOPs must be followed.

The Animal Biosafety Levels 1-4 in <u>NIH Guidelines</u> and the <u>BMBL</u> describe in detail the animal facilities and practices applicable to work with animals that have been infected with agents assigned to Biosafety Levels 1-4. These four biosafety combinations provide increasing levels of protection to research staff and to the environment and are recommended as minimal standards for activities involving infected laboratory animals. There is no research requiring ABSL-4 containment at the UW.

Existing standards and regulations govern animal facilities, operational practices, and the quality of animal care. These standards and regulations are beyond the scope of this manual. Additional information on those aspects of animal facilities is available from the IACUC.

Animals that have received a biohazardous agent should be housed in separate animal rooms, preferably in limited access rooms on a separate ventilation system. Animal room doors, as well as individual cages, should be conspicuously labeled with information regarding the agent used, date of exposure, the biohazard symbol, and the names and telephone numbers of the PI and responsible technician.

## 4. Animal Work Practices and Engineering Controls

The following work practices and engineering controls apply in addition to the biosafety practices discussed in Section 4.C of this manual.

- **a. Gloves** Personnel who handle animals must wear gloves appropriate for the task. Wash hands after removing gloves.
- **b. Additional PPE** Personnel handling animals that have received biohazardous agents must wear a face mask, gloves, and gown or other appropriate PPE. Other PPE should be considered for work with large animals.
- **c. Animal cages** Animals that are infected with a biohazardous agent are isolated within specific barriers such as filter-top cages, isolation racks, or ventilated racks. In all of these



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- systems, the effectiveness of the barrier is determined by its design and the personnel using it. Thus, employee training is of paramount importance.
- d. Transport of animals Extreme care must be taken in transferring animals from biohazard animal rooms to laboratories or other facilities. The animal must be in a sealed container or filter-top cage, and transport equipment must be sanitized or sterilized immediately after transport.
- e. Necropsy Personnel conducting necropsies must wear appropriate PPE. Post-mortem examinations of small animals exposed to biohazards should be conducted in Class II BSCs when possible. If such equipment is not available, extreme care must be taken to guard against the creation of aerosols and the contamination of conventional necropsy facilities. The necropsy table should be stainless steel and have suitable flushing devices. Appropriate disinfectant should be used to completely and thoroughly disinfect all instruments and working surfaces that come into contact with animal tissues.
- **f. Perfusions** Perfusions of animals infected with biohazardous agents must be performed in a fume hood or a non-recirculating BSC.

## 5. Occupational Health Program

All employees assigned to animal facilities, or having significant contact with animals or potentially contaminated animal wastes, should have pre-employment and periodic medical examinations. This service is provided by the <a href="Employee Health Center">Employee Health Center</a>.

The <u>Animal Use Medical Screening (AUMS)</u> program is a component of the UW's animal use Occupational Health and Safety Program required by Federal authorities. For more information on the UW AUMS program refer to Section 5 of this manual.

## 6. Pest Control Program

The University provides a pest control program to control or eliminate crawling and flying insects, wild rodents, or similar pests. All pest associated breeding sites should be sealed or eliminated. Pesticides or traps are to be used as appropriate in conjunction with a strict program of sanitary maintenance. To prevent toxic effects and possible interference with experimental procedures, pesticides (including insecticide-impregnated plastics) must be administered by a licensed professional. Contact EH&S Public Health at <a href="mailto:phdept@uw.edu">phdept@uw.edu</a> or 206-616-1623 concerning pest control issues.

## 7. Animal Waste Handling Procedures

Animal waste collection and disposal should be scheduled on a regular and timely basis. When storage of animal waste is required, the area selected should be physically separate from other storage facilities and free of insects and rodents. Refrigerated storage facilities are recommended when waste must be held in excess of four to six hours.

#### a. Disposal of Animal Carcasses and Body Parts

Animal carcasses and animal body parts are a type of biological waste that requires special handling depending on whether it is radioactive, infectious, or non-hazardous. Consult <a href="Animal Research Waste Flow Chart">Animal Research Waste Flow Chart</a> to determine how to dispose of animal carcasses and parts.



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#### b. Disposal of Animal Blood and Blood Products

Animal blood and blood products and animal waste/bedding from animals infected with recDNA or other biohazardous agents are handled as biomedical waste that can be chemically decontaminated or autoclaved according to established guidelines prior to disposal. In particular, blood, blood products, tissue, and tissue suspension, including blood contaminated items, must be decontaminated prior to disposal. Exempted are small amounts of non-primate blood, which can be flushed down sink drains without chemical treatment.

Additional information on waste disposal is found in Section 4.G and online at EH&S <u>Biohazardous Waste</u>.

#### G. DECONTAMINATION

The primary target of decontamination is the microorganism that is under active investigation. Laboratory preparations of infectious agents usually have titers grossly in excess of those normally observed in nature. The decontamination of these high titer materials can present certain problems.

Maintenance systems for bacteria or viruses are specifically selected to preserve the viability of the agent. Agar, proteinaceous nutrients, and cellular materials can be extremely effective in physically retarding or chemically binding active moieties of chemical decontaminants. Such interference with the desired action of decontaminants may require the use of decontaminant concentrations and contact times in excess of those shown to be effective in the test tube.

Similarly, a major portion of decontaminant contact time required to achieve a given level of agent inactivation may be expended in inactivating a relatively small number of the more resistant members of the population. The current state of the art provides little information on which to predict the probable virulence of these survivors. These problems are, however, common to all potentially infectious agents and must always be considered in selecting decontaminants and procedures for their use. Additional information on decontaminants can be found in "Disinfection, Sterilization and Preservation" by S.S. Block (4th edition).

### 1. Resistance

Microorganisms exhibit a range of resistance to chemical decontaminants. In terms of practical decontamination, most vegetative bacteria, fungi, and lipid containing viruses are relatively susceptible to chemical decontamination. The non-lipid containing viruses and bacteria with a waxy coating such as tubercle bacillus occupy a mid-range of resistance. Bacterial spores are the most resistant.

The relative resistance to the action of chemical decontaminants can be substantially altered by factors such as concentration of active ingredient, duration of contact, pH, temperature, humidity, and presence of extrinsic organic matter. Depending upon how these factors are manipulated, the degree of success achieved with chemical decontaminants may range from minimal inactivation of target microorganisms to an indicated sterility, within the limits of sensitivity of the assay systems employed.

## 2. Ineffectiveness

Ineffectiveness of a decontaminant is due primarily to the failure to contact the microorganisms rather than failure of the decontaminant to act. If an item is placed in a liquid decontaminant,



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the item becomes covered with tiny bubbles. The area under the bubbles is dry, and microorganisms in these dry areas will not be affected by the decontaminant. If there are spots of grease, rust, or dirt on the object, microorganisms under these protective coatings will also not be contacted by the decontaminant. Scrubbing an item when immersed in a decontaminant is helpful.

#### 3. Residual Action

Many chemical decontaminants have residual properties that may be considered a desirable feature in terms of aiding in the control of background contamination. However, consider residual properties carefully. Ethylene oxide can leave residues which cause skin irritation. In a concentrated form, phenol readily penetrates the skin and causes severe burns. Animal cell cultures, as well as viruses of interest, are also inhibited or inactivated by decontaminants persisting after routine cleaning procedures. Therefore, reusable items that are routinely held in liquid decontaminants prior to autoclaving and cleaning require careful selection of detergents for washing and must be thoroughly rinsed.

## 4. Exposure Time

Specific exposure times for the decontamination of soiled items by autoclaving, dry heat, or chemical decontaminants cannot be specifically stated. The volume of material treated, its contamination level, the soil load and type(s), moisture content, and other factors all play a role in the inactivation rate of microorganisms.

Inactivation of microorganisms by chemical decontaminants may be achieved in one or more of the following ways:

- a. Coagulation and denaturation of protein
- b. Lysis
- c. Binding to enzymes, inactivation of an essential enzyme by binding, or destruction of enzyme substrate
- d. Oxidation

Dozens of decontaminants are available under a wide variety of trade names. Table 4-1 provides information on commonly used laboratory decontaminants. A decontaminant selected on the basis of its effectiveness against microorganisms on any range of the resistance scale will be effective against microorganisms lower on the scale. Therefore, if decontaminants that effectively control spores are selected for routine laboratory decontamination, it can be assumed that any other microorganisms generated by laboratory operations, even in high concentrations, would also be inactivated.

Practical concentrations and contact times that may differ markedly from the recommendations of manufacturers of proprietary products are suggested. It has been assumed that microorganisms will be afforded a high degree of potential protection by organic matter in the material being decontaminated. It has not been assumed that a sterile state will result from application of the indicated concentrations and contact times.

It should be emphasized that these data are only indicative of efficacy under artificial test conditions. The efficacy of any of the decontaminants should be conclusively determined by individual PIs. It is readily evident that each of the decontaminants has a range of advantages and disadvantages as well as a range of potential for inactivation of a diverse microflora. Equally



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evident is the need for compromise as an alternative to maintaining a veritable "drug store" of decontaminants.

To assist in the selection of an appropriate decontaminant, consider the answers to the following questions:

- What is the target microorganism(s)?
- What decontaminants, in what form, are known to, or can be expected to, inactivate the target microorganism(s)?
- What degree of inactivation is required?
- Is the situation complicated by the presence of organic matter such as blood, agar, etc.?
- What types of surfaces are being targeted: solid or porous and/or airborne?
- What is the highest anticipated concentration of cells?
- Can the decontaminant, either as an aqueous solution, a vapor, or a gas, reasonably be expected to contact the microorganisms and can effective duration of contact be maintained?
- What restrictions apply with respect to compatibility of materials?
- Do the anticipated procedures require immediate availability of an effective concentration of the decontaminant, or will sufficient time be available for preparation of the working concentration shortly before its anticipated use?
- Will the toxicity of the decontaminant harm the researcher or other workers in the area?

Several terms are used when discussing decontamination:

- a. Sterilization refers to methods that destroy all forms of microbial life.
- b. Disinfection refers to methods that remove or destroy pathogens.
- c. Sanitization refers to methods that reduce the level of microorganisms.
- d. The ending "cide" (as in "bactericide") refers to killing.
- e. The ending "stat" (as in "bacteriostat") refers to inhibiting growth.

#### 5. Sterilization

#### a. Wet Heat (Autoclave or Steam Sterilizer)

The use of an autoclave or steam sterilizer is the preferred method for treating biohazardous waste as well as decontaminating labware. See Section 4.H for additional information on autoclaving.

#### b. Dry Heat

The use of dry heat for the decontamination of biohazardous materials and contaminated items is less efficient than autoclaving and requires a longer exposure time with higher temperature. It may be possible to decontaminate materials or soiled items by exposing them to 160°C (320°F) for four hours. This is suitable for destruction of viable agents on impermeable non-organic material such as glass but is not reliable in even shallow layers of organic material that can act as insulation. If items are heat sensitive, a temperature of



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120°C (248°F) can be used and the exposure time necessary for decontamination is usually greater than 24 hours.

The use of biological indicators with dry heat is necessary to determine the most effective temperature and/or exposure time for decontamination of materials or equipment. Use spore tests designed specifically for dry heat, and follow the manufacturer's instructions for incubation.

#### c. Chemical Sterilant

In the laboratory, chemical decontamination is necessary because the use of pressurized steam, the most rapid and reliable method of sterilization, is not normally feasible for decontaminating large spaces, surfaces, and stationary equipment. Moreover, high temperatures and moisture will damage delicate instruments.

## 1) Ethylene Oxide

Ethylene oxide is not a practical decontaminant in most laboratory settings due to the potential toxic exposure to the worker. Ethylene oxide is used in hospital sterilizers for sterilizing heat sensitive equipment. The sterilizers are provided with dedicated ventilation canopies and monitoring equipment.

## 2) Paraformaldehyde and Formaldehyde Gas

Formaldehyde gas can be liberated by heating paraformaldehyde to depolymerize it. This vapor is an effective space decontaminant for decontaminating biological safety cabinets, rooms or buildings, but in the vapor state with water, it tends to polymerize on surfaces and form paraformaldehyde, which remains persistent.

In the absence of high moisture content in the air, formaldehyde released in the gaseous state forms fewer polymerized residues on surfaces and less time is required to clear treated areas of fumes than formaldehyde released in the vapor state.

The pungent, irritating odors and its classification as a potential cancer hazard limit the use of formaldehyde in the laboratory. Refer to the <u>UW Laboratory Safety Manual</u> for information on chemical hazards.

#### 3) Glutaraldehyde

In the past, 1%-2% solutions of glutaraldehyde have been used as cold sterilants on instruments that could not be heated. These solutions are being replaced by peratic acid solutions due to concerns about the toxicity of the glutaraldehydes.

#### 6. Disinfection

The following chemical decontaminants are recommended when attempting to chemically disinfect materials. Disinfection is defined as destroying certain pathogens.

#### a. Halogens

The halogens (chlorine, iodine, bromine, and fluorine) will rapidly kill bacterial spores, viruses, rickettsiae, and fungi. These decontaminants are effective over a wide range of temperatures. In fact, chlorine has been shown to be effective at 4000°F. (On the other hand, phenols and formaldehyde have high temperature coefficients.) The halogens have several undesirable features. They readily combine with protein, so that an excess of the halogen



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must be used if proteins are present. The halogens are relatively unstable so that fresh solutions must be prepared. The frequency of preparation is discussed below. Finally, the halogens corrode metals. A number of manufacturers of decontaminants have treated the halogens to remove some of the undesirable features. For example, sodium hypochlorite reacts with paratoluenesulfonamide to form Chloramine T, and iodine reacts with certain surface-active agents to form the popular iodophors. These "tamed" halogens are stable, non-toxic, odorless, and relatively noncorrosive to metals. However, the halogens are highly reactive elements and, because they are reactive, they are good germicides. When a halogen acts as a decontaminant, free halogen is the effective agent. Raising the pH or combining the halogen with other compounds to decrease the corrosive effect also decreases the decontaminating effect of a halogen.

#### 1) Chlorine

This halogen is a universal decontaminant that is active against all microorganisms, including bacterial spores. Free, available chlorine is an active element. It is a strong oxidizing agent and corrosive to metals. Sodium hypochlorite is usually used as a base for chlorine decontaminants and is more stable than other forms of chlorine. An excellent decontaminant can be prepared from household or laundry bleach, which usually contain 5.25% available chlorine or 52,500 ppm. If diluted 1:10, the solution will contain 5,250 ppm of available chlorine and have a lower pH and more free available chlorine. This solution is appropriate for sanitizing items or surfaces with high levels of organic matter. A 1:100 dilution with 525 ppm of available chlorine is appropriate for sanitizing items or surfaces with low levels of organic matter.

Chlorine combines with protein and rapidly decreases in concentration in its presence. Chlorine solutions will gradually lose strength so that fresh solutions must be prepared unless the free available chlorine in the solution is checked. Currently, there are no practical means of verifying the level of free available chlorine at the level used in the laboratory.

Never mix bleach with ammonia or hydrochloric acid containing cleaners because toxic fumes are created.

#### 2) lodine

The characteristics of chlorine and iodine are similar. One of the most popular groups of decontaminants used in the laboratory is the iodophors; Wescodyne is perhaps the most popular. The dilution range of Wescodyne recommended by the manufacturer is one ounce in five gallons of water (which yields 25 ppm of available iodine) to three ounces in five gallons (which yields 75 ppm. At 75 ppm, the concentration of free iodine is .0075%. This small amount can be rapidly taken up by any extraneous protein present. Clean surfaces or clear water can be effectively treated by 75 ppm available iodine. However, difficulties may be experienced if any appreciable amount of protein is present. For bacterial spores, a dilution of one to 40 (which yields 750 ppm) is recommended by the manufacturer. There are test strips available commercially to verify the strength of available iodine in the range of 25-75 ppm. These strips can be used in verifying the stability of prepared solutions.



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#### b. Formalin

Formaldehyde for use as a decontaminant is usually marketed as a 37% solution referred to as formalin. Formaldehyde in a concentration of 5% active ingredient is an effective liquid decontaminant. It loses considerable activity at refrigeration temperatures.

Formalin has many of the same hazards mentioned for paraformaldehyde.

## c. Hydrogen Peroxide and Peracetic Acid

Both are fast acting and effective. They are useful in the decontamination of medical instruments when used in specially designed washing units.

#### 7. Sanitization

Sanitization refers to reducing the level of microorganisms present.

#### a. Alcohol

Ethyl or isopropyl alcohol in a concentration of 70 80% by weight is often used. Alcohols denature proteins and are somewhat slow in their action. They are effective decontaminants against many vegetative bacteria and lipid containing viruses; however, they are not effective for viruses such as hepatitis B, spore forming bacteria, or the vegetative form of some gram negative organisms.

One of the disadvantages of the use of alcohols is their flammability. They should not be used in operations that require the use of an open flame.

## b. Quaternary Ammonium Compounds or Quats

These compounds are not effective against gram negative organisms. Quats are cationic detergents, strongly surface active, and effective against viruses containing lipids. Quats will attach to protein so that dilute solutions of quats will quickly lose effectiveness in the presence of proteins. Quats tend to clump microorganisms and are neutralized by anionic detergents such as soap. Quats have the advantages of being non-toxic, odorless, nonstaining, non-corrosive to metals, stable, and inexpensive.

#### c. Phenolic Compounds

Although phenol itself may not be in widespread use, phenol homologs and phenolic compounds are basic to a number of popular decontaminants. The phenolic compounds are effective decontaminants against some viruses, rickettsiae, fungi, and vegetative bacteria. The phenolics are not effective in ordinary usage against bacterial spores.

#### d. UV Light

Ultraviolet (UV) lamps are not recommend in a BSC nor are they necessary. Do not use UV lamps as the primary source of disinfection. If used, clean lamps weekly to remove dust and dirt that may block the germicidal effectiveness. Turn off UV lamps when the room is occupied to protect eyes and skin from UV exposure, which can burn the cornea and cause skin cancer. Close the sash when operating the UV lamp.

#### 8. General Procedures

a. Biohazardous liquid and solid wastes, as well as all items such as labware, equipment, or apparatuses contaminated with biohazards, must be decontaminated before being



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- washed, sorted, or discarded. Each individual working with biohazardous material or contaminated items is responsible for its decontamination.
- b. Whenever possible, contaminated items or biohazardous liquid or solid waste should be decontaminated by autoclaving.
- c. All floors, laboratory benches, and other surfaces or areas where biohazardous materials are handled should be chemically decontaminated as often as deemed necessary by the PI/lab manager. The choice of the chemical decontaminant used is at the discretion of the PI/lab manager.
- d. Upon completion of operations involving plating, pipetting, centrifugation, and similar procedures with biohazardous materials, the surrounding area should be chemically decontaminated.
- e. Floors should be wet mopped. Dry sweeping and dusting leads to the formation of secondary aerosols.
- f. Stock solutions of suitable chemical decontaminants should be maintained on each laboratory bench.

## 9. Selecting Chemical Decontaminants for Research on recDNA Molecules

Nucleic acids often have better survival characteristics under adverse conditions than do the intact virions and cells from which they were derived. Oxidizing agents such as bleach will destroy the nucleic acid. However, the chosen decontaminant's ability to destroy the nucleic acid should be confirmed in the laboratory.



5. U=POTENTIAL USE

3. XX=G00D

X=FAIR TO GOOD DEPENDING
4. Y=HAS INDICATED
CHARACTERISTICS.

1. REQUIRES TEMPERATURES OF 37°F AND 30% RELATIVE HUMIDITY 2. REQUIRES TEMPERATURES OF 23°C AND > 60% RELATIVE HUMIDITY

FT=REQUIRES FURTHER TESTING

N.E.=NOT EFFECTIVE

N/A=NOT APPLICABLE

Table 4-1: Summary of Practical Laboratory Decontaminants

Common Trade Names		Bleach	Wescodyne Biocide	Formalin			Staphene, Amphyl	Megasol	Liquid or Vapor	Cidex, Procide, Metricide			
	Books and papers								Ħ			$\supset$	
	Air handling systems								Ħ				$\supset$
	Large are <u>decon</u>								ㅂ				$\supset$
S S	Lenses and electronic instruments								ㅂ			⊃	$\supset$
Potential Uses <sup>5</sup>	Stationary equipment penetrating <u>decon</u>								$\supset$	$\supset$			$\supset$
tial	Stationary equipment surface <u>decon</u>	_		$\supset$	_	О	n	Ω	$\supset$	$\supset$	$\supset$		
tent	Portable equipment penetrating decon								$\supset$	$\supset$		$\supset$	
Pot	Portable equipment surface <u>decon</u>	_			_	Ω	n	Π	Э	$\supset$	$\supset$		
	Liquids for Discard to Sewer	$\supset$											
	Dirty Glassware	$\supset$											
	Work surfaces	$\supset$	_				Π						
	DixoT	>	>	>	>	Υ	γ	Y	Υ	>	Υ	>	>
	Respiratory irritant	>		>						>	_	>	>
	Eye irritant	>	>	>	>	_	7	>	>	>	>	>	>
4	Electronics compatible Skin irritant											>	>
tics	Microscope & camera lens compatible			$\vdash$				>		>		>	>
eris	Inactivate by organic matter	>	>				Ħ	>		Ŀ			
acte	Residue	_											-
Characteristics <sup>4</sup>	Explosion Potential	>	>	>			γ			>		<b>≻</b>	$\dashv$
U				-	-	_							>
	Flammable				>	Υ	_					>	
	Corrosive	>	>	_			γ					_	_
-	Effective Shelf life > 1 week	S	>	>	>	>	Υ	>	>	>	>	N/A	N/A
m	suriV wol2	×	×			- 1	-		Ħ	- 1	FT	Ħ	-
ated	Bacterial Spores	×	×	×					×	×	×	×	×
activ	suriV biqil-noM	×	×	×	×	×	×		Ħ	×	×	×	×
Agents Inactivated <sup>3</sup>	suriV biqi⊿	×	×	×	×	×	×	×	×	×	×	×	×
Age	Vegetative Bacteria	×	×	×	×	×	×	×	×	×	×	×	×
Time	Minutes required to inactive lipid viruses	10	10	10	10	10	10	10	10	10	10	09	09
Contact Time	Minutes required to inactivate bacterial spores	30	30	30	N.E.	N.E.	N.E.	N.E.	30	30	30	9	09
Concentrations	Active Ingredient Concentration	5250 ppm	75-750	1-8%	85%	%02	2%	2%	3-6%	0.02	0.02	45 g/L	3 g/ft³
Chemical Decontaminants		Chlorine Compounds	lodophor	Formaldehyde	Ethyl Alcohol	Isopropyl Alcohol	Phenolic compounds	Quaternary ammonium compounds	Hydrogen Peroxide	Glutaraldeyde	Peracetic Acid	Ethylene Oxide¹	Paraformaldehyde²

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#### H. BIOHAZARDOUS WASTE

Responsibility and procedures for biohazardous waste are described below. Refer to each section to learn how to identify, package, transport, and decontaminate different types of biohazardous waste.

## 1. Responsibility

PIs are responsible for developing protocols for properly identifying, packaging and decontaminating biohazardous waste, including all recDNA waste, prior to disposal.

Refer to <u>EH&S Biohazardous Waste</u> for detailed biohazardous waste information. Also refer to the <u>UW Biohazardous Waste Management Plan</u>.

## 2. Identifying Biohazardous Waste

The following materials are defined as biohazardous (biomedical) waste:

a. Sharps waste is regulated by state law. Sharps waste must not be disposed of in the regular waste stream. The term "sharps" is a regulatory waste classification that refers to items used to puncture, cut, or scrape body parts and that, in a waste container, can cause punctures or cuts to solid waste handlers or to the public. Therefore, all sharps waste must be placed in appropriate sharps containers and decontaminated prior to disposal.

**Sharps** include the following:

- i. Needles, syringes with needles and IV tubing with needles attached
- ii. Lancets
- iii. Scalpel blades
- iv. Other sharps items not defined above only if contaminated with biohazardous material including recDNA (e.g. broken glass; razor blades; fragile glass tubes, vials, or ampoules including glass Pasteur pipettes; glass slides and cover slips)
- b. Human and non-human primate blood, blood products, body fluids, tissues, and cells: includes human and non-human primate blood, blood components, and materials containing free-flowing blood and blood products. Both human and non-human primate cell lines, regardless of origin, are also defined as biohazardous waste.
- c. Cultures and stocks of etiologic agents and associated biologicals: include but are not limited to specimen cultures, discarded live and attenuated vaccines, cultures and stocks of etiologic agents, and wastes from the production of biologicals and serums.
- d. RecDNA: includes but is not limited to waste products from laboratory research procedures involving recDNA in plasmids, viral vectors, *E. coli*, yeast, cell cultures, as well as naked DNA from polymerase chain reaction (PCR) and sequencing reactions. This also includes tissue and cells harvested from animals containing recDNA (e.g., transgenic animals).
- e. Laboratory waste that has come in contact with a biohazard as listed in a, b, c, or d. above: includes but is not limited to culture dishes, blood specimen tubes, devices used to transfer, inoculate, and mix cultures, and other materials that have come in contact



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with biohazards (including disposable PPE and clothing). Laboratory waste includes solid biohazardous waste and biohazardous laboratory glass and plastic items.

- f. Animal waste, animal carcasses, and body parts exposed to pathogens or recDNA: includes animal bedding and other waste from such animals and all non-human primate tissue and carcasses.
- g. Human pathological waste: includes human source biopsy materials, tissues, and anatomical parts. This does not include teeth, human corpses, remains, and anatomical parts that are intended for interment or cremation.
- h. Plant waste: includes all transgenic plants, seeds, spores, plant debris, and soil materials, plus any plants exposed to plant pathogens.

## 3. Packaging and Handling of Biohazardous Waste

## a. Sharps Waste

Collect sharps in a leak-proof, rigid, puncture-resistant, durable red plastic sharps container. These containers are red in color, labeled with a biohazard symbol, and equipped with a tight-fitting lid for use during handling and transport. Refer to Section 4.D.2 for additional information on sharps.

Sharps containers must be autoclaved when 2/3 filled and within 90 days of filling the container. When autoclaving on-site, place a strip of autoclave tape running from the lid and down across the biohazard symbol on the container to secure the lid prior to autoclaving. Do not cover the vent holes on the lid during the autoclave cycle. Label the container with the room number and the PI name. Sharps waste must be kept separate from regular waste at all times. Follow your <u>location-specific procedures</u> for collection of sterilized sharps containers.

For additional information and to download posters, refer to the <u>EH&S Sharps and Laboratory Glass webpage</u>.

#### b. Solid Biohazardous Waste

Collect solid recDNA or other biohazardous waste (e.g., contaminated gloves, culture dishes) in plastic, autoclavable biohazard waste bags contained inside a rigid container. The outer container must be labeled or clearly display the biohazard symbol. A polypropylene bin can be used to hold biohazardous waste bags and can be placed in the autoclave with the waste bags. The recommended closure device is a loosely tied rubber band. Autoclave tape must be used on biohazard bags to notify Custodial Services that the waste has been treated. After autoclaving, bagged waste may be placed alongside the regular waste container for the laboratory.

Biohazardous waste bags must be decontaminated by autoclave prior to disposal within eight days from the generation of the waste if stored above 32°F/0°C. If stored at or below 32°F/0°C, the waste may be stored for 90 days before autoclaving.

Refer to part 5 below for procedures for decontaminating solid biohazardous waste.

## c. Biohazardous Laboratory Glass and Plastic

Biohazardous lab glass and plastic includes items contaminated with biohazards that could puncture a plastic bag. Place contaminated items in a container that cannot be



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punctured and can be easily autoclaved, such as a pipette box/keeper. Or package items in a sturdy cardboard box lined with a biohazard bag. Label the box with the biohazard symbol and PI name and room number. Seal with "Laboratory Glass" tape or label as such. Use the <u>Packaging Sharps and Lab Glass Waste poster</u> for guidance.

#### d. Liquid Biohazardous Waste

Collect liquid biohazardous waste containing free flowing liquids in leak proof, rigid, durable containers labeled with the biohazard symbol and the word "biohazard." If transporting, close and seal containers and place in a leak-proof secondary container.

## 4. Transporting Biohazardous Waste

This section outlines the proper procedures for transporting biohazardous waste within buildings and between buildings. Biohazardous waste must be packaged so that PPE is not needed during transport. If PPE is necessary, then the waste is not properly packaged.

#### a. Within Building

## 1) Sharps Containers

Sharps containers transported within the same building must be securely closed and the outer surface decontaminated prior to transport. Attach a piece of autoclave tape over the lid and sides being careful not to cover air vents. This will help secure the lid if the plastic expands and contracts during steam sterilization. Label the container with name of the PI and the room number.

If leaking is possible, place inside a secondary container. The secondary container must be closable, puncture resistant, and constructed to contain all contents and prevent leakage. This container should either be red in color or labeled with the biohazard symbol.

#### 2) Other Biohazardous Waste

Bagged biohazardous waste transported within the same building must be closed, surface decontaminated, and placed inside a secondary containment prior to transport. Biohazardous waste cannot be transported in biohazard bags alone. If the secondary container is closed, it must be identifiable as biohazardous either by being red in color or labeled with the biohazard symbol.

#### 3) Animal Carcasses

Contact the <u>Department of Comparative Medicine</u> prior to transporting animal carcasses for instruction in packaging and transportation.

#### b. Between Buildings

Any biohazardous waste transported between buildings by motor vehicle must be transported in a UW owned and operated vehicle (e.g., Fleet Services, UCAR, or UW shuttle).

Sharps containers transported between buildings, have the same requirements as within the same building (see above). Bagged biohazardous waste transported between buildings has the same requirements as within the same building (see above), with the exception that the secondary container must have a secured lid.



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## 5. Decontaminating Biohazardous Waste

How you decontaminate your biohazardous waste depends on your location and if you have access to an autoclave or an autoclave cost center. If you do not have access to either, biohazardous waste must be shipped off-site for treatment and disposal. Refer to the sections below for the different methods to decontaminate biohazardous waste.

#### a. On-Site Sterilization (Autoclave)

If you have access to an autoclave or you have access to a departmental or facility autoclave, you can treat and dispose of solid biohazardous waste yourself. Steam sterilization with an autoclave effectively inactivates most infectious agents.

If you are operating your own autoclave to decontaminate biohazardous waste, autoclave monitoring requirements must be in place. Refer to the procedures listed in part 7 below.

#### b. Autoclave Cost Centers

Depending on your location, you can pay an autoclave cost center to treat and dispose of solid biohazardous waste and sharps waste. Autoclave cost centers charge a fee for autoclaving and disposal of waste. Each center has its own rules and procedures. Contact them directly for more information. Autoclave cost centers include:

- Laboratory Services at Magnuson Health Sciences Center
- <u>Laboratory Services at South Lake Union</u> (UW NetID log-in required)

#### c. Off-Site Sterilization

If you do not have access to an on-site autoclave or an autoclave cost center, biohazardous waste can be collected by a UW waste contractor for off-site treatment and disposal. <a href="EH&S">EH&S</a> Shipping Regulated Medical Waste (RMW) Training is required every three years for all personnel who will package and ship waste. Contact Laboratory Services in Health Sciences Academic Services and Facilities to <a href="Set up an account">Set up an account</a> with a UW waste contractor.

Shipping for off-site treatment and disposal is required for some types of waste, such as trace chemo waste, certain pathological waste, and biosafety level 3 (BSL-3) animal carcasses, tissue and bedding. These wastes require incineration prior to disposal.

#### d. Liquid Biohazardous Waste

Liquid biohazardous waste must be treated before disposal via the sanitary sewer and cannot be disposed of as solid waste.

#### 1) To treat free-flowing liquid biohazardous waste with bleach:

- i. Collect in leak-proof, rigid containers labelled with a biohazard symbol.
- If transporting, close and seal containers, and place in a leak-proof secondary container.
- iii. Add chlorine bleach to equal a final concentration of 10% bleach by volume.
- iv. Let the solution site for at least 30 minutes before disposing via the sanitary sewer.



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## 2) If you have access to your own on-site autoclave, you can also autoclave liquid biohazardous waste:

- i. Remove or loosen caps before loading into the autoclave.
- ii. Use the appropriate autoclave cycle to achieve sterilization conditions as described in part 7 below.
- iii. After the autoclaved liquid has cooled, dispose of the fluid via the sanitary sewer.

#### 3) Volumes >10 Liters

Prior to disposing of human and non-human primate blood, blood products, and other free-flowing body fluids in 10 liter or great volumes, contact EH&S Research and Occupational Safety at <a href="mailto:ehsbio@uw.edu">ehsbio@uw.edu</a> or 206.221-7770.

## 4) Animal blood other than primate blood

Small quantities may be flushed into the sewer system without treatment. Due to coagulation when handling large quantities, flushing is impractical. If the blood is potentially infected with a pathogen, handle according to the guidelines for human blood. Contact EH&S for questions at <a href="mailto:ehsbio@uw.edu">ehsbio@uw.edu</a> or 206.221.7770.

### e. Pathological Waste

Incineration or cremation is required for human pathological waste and non-human primate carcasses and body parts. Make disposal arrangements before obtaining human or non-human primate pathological samples. Do not dispose of pathological waste with other biohazardous wastes.

- For human pathological waste, contact the Department of Biological Structure at 206-685-2274 or set up an account to ship waste for off-site incineration (see 5.c above).
- For non-human primate pathological waste, contact the Washington National Primate Research Center (WaNPRC) at 206-543-8686.
- For extracted teeth, arrange for off-site incineration (see 5.c above). If extracted teeth contain amalgam, contact EH&S at 206-616-5835 to arrange for collection as hazardous waste.

## f. Animal Waste

The disposal for animal carcasses, animal parts, bedding, and waste is coordinated through the Department of Comparative Medicine (DCM). Consult DCM for current guidelines for packaging, handling, and returning these materials to their facility for disposal. Refer to the <a href="Animal Research Biohazardous Waste Flow Chart">Animal Research Biohazardous Waste Flow Chart</a> and the <a href="site-specific flow chart">site-specific flow chart</a> for disposal of these materials at your location.

#### g. Mixed Wastes

- Radioactive/biohazardous animals: Contact EH&S Radiation Safety at 206-543-0463 for additional information.
- Mixed biological waste and chemical waste: Avoid creating mixed waste when
  possible. Contact EH&S ROS at <a href="mailto:ehsbio@uw.edu">ehsbio@uw.edu</a> or 206-221-7770 prior to generating
  the waste.



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 Radioactive/non-infectious animals: Dead animals treated with radioactive materials are disposed of in accordance with procedures listed in the <u>UW Radiation Safety</u> Manual.

#### h. Other Wastes

For any other biohazardous or biomedical waste: Contact EH&S ROS at <a href="mailto:ehsbio@uw.edu">ehsbio@uw.edu</a> or 206-221-7770 for advice and assistance.

## 6. Site-Specific Information

Refer to the Biohazardous Waste Flow Charts for site-specific information.

- Animal Research Waste
- Harborview Medical Center
- Harborview Research & Training Building
- <u>Life Sciences Building</u>
- Magnuson Health Sciences Building
- Main Campus and Leased Facilities
- South Lake Union
- University of Washington Medical Center
- WaNPRC Facilities

If your location does not have a flow chart, follow the Main Campus and Leased Facilities flow chart.

### 7. Autoclave Quality Control

A properly operating autoclave renders biohazardous waste sterile so that it can be disposed of safely via municipal waste. Any University of Washington laboratory or facility that uses an autoclave to decontaminate biohazardous waste is required to follow the <u>General Autoclave Safety Guidelines</u>, the <u>Autoclaving Biohazardous Waste Guidelines</u>, and implement a site-specific procedure for autoclaving biohazardous waste (<u>template SOP</u> available).

The <u>Seattle/King County Infectious Waste regulations</u> require all operators of autoclaves to be trained. The training procedure must be written, and all users must have access to the written procedures. All users must receive this training prior to operating the autoclave. It is the responsibility of the PI or laboratory/facility manager and/or department to ensure compliance with all autoclave safety guidelines and the <u>UW Biohazardous Waste Management Plan</u>. Autoclave records must be maintained for six years.

#### a. Autoclave Operation

Consult the manufacturer's manual for your autoclave to select or program a cycle. For sterilization of biohazardous waste, the cycle must include a minimum temperature of 121°C or 250°F for 30 minutes or longer, depending on size and compaction of the load. The full cycle time will take 60-90 minutes. Greater time and/or temperature may be necessary to sterilize certain loads.



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## b. Autoclave Monitoring

To ensure adequate waste sterilization, monitor each autoclave as shown in Table 4-2.

**Table 4-2: Autoclave Monitoring Requirements** 

Type of Monitoring	Required Frequency	Instructions
Temperature	Each cycle Annually	<ul> <li>Ensure autoclave has a recording and/or indicating thermometer or other method to verify temperature.</li> <li>Check and record that sterilization temperature (121°C) was achieved and sustained for at least 30 minutes.</li> <li>Calibrate thermometer.</li> </ul>
Heat-sensitive tape (autoclave tape)	Each cycle	<ul> <li>Use heat-sensitive tape to visually indicate steam sterilization.</li> <li>Tape only indicates that proper temperature was reached; it does not indicate heat was sustained for sufficient time.</li> </ul>
Chemical integrator	Each cycle	<ul> <li>Place an approved integrator in the center of load to confirm attainment of adequate sterilization.</li> <li>Note: The only integrators approved for use by the Seattle-King County Health Department are 3M Comply Thermalog or Thermalog-S, 3M Comply SteriGage, and Steriscan.</li> </ul>
Biological indicator	Monthly	<ul> <li>Use the biological indicator <i>Bacillus stearothermophilus</i> at the center of a load to confirm the attainment of adequate sterilization conditions.</li> <li>Instructions are included on the <u>Quality Control Checklist</u>.</li> </ul>
Structural inspection	Every 2 years	<ul> <li>If autoclave is over five cubic feet in volume, contact         Facilities Services Maintenance &amp; Alterations for an         autoclave structural inspection (required per WAC 296-</li></ul>

#### 8. Refusal to Collect Waste

Custodial Services personnel are instructed to refrain from removing any animal carcasses, parts, or other questionable wastes and to report discrepancies to their supervisors. The reports are referred to EH&S ROS at <a href="mailto:ehsbio@uw.edu">ehsbio@uw.edu</a> or 206-221-7770, for resolution.



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#### I. CONTROL OF RECDNA EXPERIMENTATION

## 1. Responsibility

Procedures for obtaining approval for research involving the use of recDNA techniques at the UW can be found in Section 2.

When working with recDNA materials, effective biological safety programs involve selecting the appropriate biological containment method, including the physical containment facilities.

It is the responsibility of the PI to assess the potential risk associated with the experiment and determine an appropriate host-vector system (biological containment) and physical containment to be used for the proposed experiment. The IBC will review this assessment of risk.

## 2. Physical Containment

Standard microbiological practices are covered in Section 4.C of this manual.

Special procedures, equipment, and laboratory installations that provide physical barriers that are applied in varying degrees according to the estimated risk are covered in Section 4.D.

## 3. Biological Containment

Experiments involving recDNA molecules, by their very nature, lend themselves to biological containment. Natural barriers exist which limit either the infectivity of a vector or vehicle (plasmid, bacteriophage, or virus) to specific hosts or its dissemination and survival in the environment.

The vectors that provide the means for replication of the recDNA and/or the host cells in which they replicate can be genetically designed to decrease by many orders of magnitude the probability of dissemination of recDNA molecules outside the laboratory.

In considering biological containment, the vector (plasmid or virus) for the recDNA and the host (bacteria, plant, or animal cell) in which the vector is propagated in the laboratory will be considered together.

Discussion of the various levels of biological containment is beyond the scope of this manual. Additional information can be found in <u>NIH Guidelines</u>. Copies are also available from EH&S ROS at 206-221-7770.



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# SECTION 5 – EMPLOYEE OCCUPATIONAL HEALTH PROGRAM

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## A. OVERVIEW

As part of UW EH&S, and as mandated by the UW Administrative Policy Code (10.3), the UW Occupational Health Program strives to ensure the University of Washington campus is a safe and healthy place for all members of the academic research community and for visitors/affiliates. The Occupational Health Program goals are to:

- Conform to occupational health standards set by regulatory agencies and granting and accrediting bodies including Washington State's Department of Safety and Health (DOSH), AAALAC International, the NIH Guidelines, and the CDC, including the NIH/CDC's BMBL publication;
- 2. Assure that employees are physically able to perform their jobs; health assessments and occupational health recommendations are required for specific work assignments based on the types of hazards that are present in the work environment;
- 3. Prevent and detect disease and illness resulting from exposure to possible health hazards on the UW campus;
- 4. Establish occupational health guidelines for vaccinations, medical surveillance, and exposure response in the research setting; and
- 5. Establish baseline health data for future comparison.



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#### **B. ROLES AND RESPONSIBILITIES**

## 1. Environmental Health and Safety

EH&S is responsible for assisting the PI with risk assessments, identifying exposure controls, and developing guidance for and assisting with the implementation of medical management protocols. The goal is to prevent occupational illness resulting from exposure to health hazards in the work environment. The role of EH&S in the process of implementing the occupational health program includes the following:

- a. Provide occupational health reviews and make recommendations based on a hazard/risk assessment of the work, incorporating reviews from EH&S specialists (biosafety, chemical hygiene, etc.), the IBC, and the UW EHC;
- b. Provide follow-up for accident/injury investigation;
- c. Review and ensure workplace compliance with the BBP program and all other components of the occupational health program;
- d. Provide medical guidance pre-, during and post- work, facilitating clinical services and care; and
- e. Collaborate with Human Resources to establish safe and appropriate work assignments in keeping with current legislation.

## 2. Principal Investigators

Pls whose research involves the use of biohazards are responsible for communicating workplace hazards to laboratory staff and ensuring that occupational health and safety requirements are followed. In addition, Pls must offer appropriate immunizations and/or medical surveillance as specified by EH&S. All of the following actions are necessary to fulfill these responsibilities:

- a. Inform both male and female employees about the reproductive and teratogenic risks when there is a potential for exposure to infectious agents in the work area. Also inform staff about the online document <a href="EH&S Guidance About Workplace Hazards Impacting Reproduction">EH&S Guidance About Workplace Hazards Impacting Reproduction and Development</a>;
- b. Inform employees about immunologic risks when there is a potential for exposure to biohazardous agents in the work area;
- c. Inform employees about the possible risks associated with work using viruses that contain oncogenes or that may be oncogenic;
- Inform staff that if they have questions or concerns about their health in relation to work with biohazardous agents, they are strongly encouraged to contact the UW EHC for a confidential medical consultation;
- e. Instruct employees that they must contact the UW EHC if they develop signs or symptoms consistent with exposure to the biohazardous agents in use. If employees see their personal health care provider (HCP) with symptoms, they should inform the HCP of the agents they are working with or to which they may have been exposed. They must inform the UW EHC after being treated by their HCP;
- f. Instruct employees that if they have allergies that may limit the administration of specified immunizations or contraindicate prophylactic measures needed after an



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exposure incident, they must contact the UW EHC for evaluation. These employees may have an increased risk for infection when working in an environment where biohazards are in use.

- g. Maintain records for each employee documenting the requirements to work in the laboratory. These records should be available for review by EH&S. At a minimum these records should address the following for each job classification or position:
  - Specific biohazard and/or exposure risk;
  - Required medical evaluations, including documentation of an assessment with the UW EHC;
  - Recommended surveillance testing;
  - Required or recommended immunizations, documenting the date offered and frequency of administration;
  - Any applicable physical requirements;
  - Recommended serum banking and/or monitoring, documenting the frequency and date offered;
  - Instruct employees about procedures to follow in case of exposure to a
    hazardous agent. Ensure that the <u>UW exposure response procedure</u> information
    is available to staff and that the procedures are followed;
  - Instruct employees to report exposure incidents and near misses within 24 hours (eight hours if hospitalized or injury is serious) on the UW Online Accident Reporting System (OARS).

## 3. Employees

Employees engaged in activities involving biohazards are responsible for complying with the occupational health requirements and guidelines as specified by their PIs and EH&S. Employees should be aware of the hazards in their workplace and able to bring concerns or suggestions for improvement to the attention of their supervisors.

Employees should be aware of how their health status may be impacted by work with biohazardous agents. For example, immunocompromised individuals may be at increased risk of illness or may experience more severe illness should an exposure incident occur when working with certain biohazardous agents.

An immunocompromised status may result from immunosuppressive therapy (chronic steroid use, chemotherapy for cancer, immune modulators, radiation therapy, and others), diabetes mellitus, cancer, malnutrition, pregnancy, acquired immune deficiency syndrome (AIDS), and chronic alcoholism.

If personal health concerns or questions arise, employees are strongly urged to arrange for a confidential medical consultation by contacting the UW EHC.

Contact the UW EHC for medical guidance after completing first aid procedures if a possible exposure occurs. UW employees working at non-UW facilities should contact the EHC at their location (for example, Fred Hutchinson Cancer Research Center, Seattle Children's Hospital, or



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the Veterans' Administration Medical Center) or go to the nearest emergency department. Then notify the UW EHC of the exposure.

## 4. UW Employee Health Centers

The UW EHC is responsible for providing clinical services, including medical evaluations as needed for specific work, administering immunizations, providing follow-up care after an injury, providing employee counseling, and establishing and maintaining employee medical records. UW <a href="Employee Health Centers">Employee Health Centers</a> are located at Hall Health Center (campus EHC as part of EH&S), UW Medical Center (UWMC- Montlake and Northwest campuses), Harborview Medical Center (HMC), Valley Medical Center, and UW Neighborhood clinics.

#### C. IMMUNIZATION GUIDELINES

Depending on the specific work setting, the offering of immunizations may be required or recommended for employees who are potentially exposed to certain biological agents or in contact with certain animals. However, because of the wide range of biological agents or combinations of agents that may be present in a research institution, the specific immunizations or other health-related measures that are indicated will be determined based on the risk assessment performed by EH&S -EHC with review by the IBC as appropriate. The recommendations for immunization will be by EH&S to the PI/supervisor at the time of approval of the project. The PI/supervisor offers employees the specified immunizations administered by the Employee Health Center.

To reduce the risk of occupationally acquired bloodborne disease, employees with reasonably anticipated potential for exposure to human blood and its components, human bodily fluids, or other human tissues (including cell lines) must participate in the UW BBP Program and be offered the hepatitis B vaccine in accordance with the Washington State Department of Safety and Health requirements. After being informed of the risks versus benefits of immunization, a declination form must be signed if an employee declines the hepatitis B vaccine. The BBP program is covered in detail in Appendix A of this manual.

Immunization for other potentially infectious agents may be required after risk assessment by EH&S, the IBC, and the PI. In some cases there are immunization requirements for working in a facility or with an agent. For information about immunizations that may be required, contact the UW EHC at 206-685-1026.

## D. ANIMAL USE MEDICAL SCREENING (AUMS)

The OHN provides an <u>AUMS</u> to screen for health risks in persons who work in the animal care and use environment. The AUMS is offered to all veterinary and animal husbandry staff, researchers and their staff, the IACUC members, volunteers, visiting scientists, students, and other individuals working in or entering areas with animals, animal tissues, or animal fluids. Employees must complete the animal use health screening prior to work in any University animal care and use environment.

The AUMS form must be completed at least every three years for research staff and at least annually for husbandry, veterinary, and other research support staff. The OHN will provide phone or inperson consultation as needed for those who have increased risk of hazards associated with animals.

See <u>Animal Use Medical Screening (AUMS)</u> for more information.



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#### E. RESEARCH PROTOCOL REVIEW

- 1. EH&S Research and Occupational Safety (ROS) specialists review all animal research protocol submissions to evaluate for occupational hazards.
- 2. EH&S ROS discusses the project with the PI, the UW EHC, other EH&S specialists, the IBC, and others (for example, the IACUC) as needed in order to provide comprehensive recommendations to be used in the laboratory or in the field.
- 3. The review includes recommendations for immunizations, medical surveillance, post-exposure evaluation guidelines, training, workplace exposure controls, PPE, and the safe use of hazardous materials.
- 4. At the end of the OH review, the occupational health recommendations (OHR) are uploaded to the Office of Animal Welfare Hoverboard database, for access and review by the PI and staff electronically. A copy is sent to the UW EHC and other health and safety personnel who may interface with the PI's laboratory.
- 5. EH&S ROS also reviews non-animal research protocols involving biohazards and provides recommendations as necessary for immunizations, medical surveillance, and post-exposure evaluation guidelines.

#### F. POST EXPOSURE TREATMENT

The <u>UW Exposure Response Poster</u> describes the actions to take in the event of a possible exposure. Should an employee experience an exposure to a hazardous or biologic agent, they must immediately perform first aid, and then call the <u>Employee Health Center</u> for evaluation. The employee must also call their supervisor and fill out the <u>OARS</u> either separately or with the supervisor's assistance.

The Washington State Department of Labor and Industries requires that an exposure determination be made for anyone who is potentially exposed to human blood and its components, human bodily fluids, or other human tissues (including cell lines). This exposure determination is covered in detail in the BBP Program section of this manual. BBP exposures are treated in accordance with the WISHA BBP regulations (WAC 296-823) and the "

<u>Updated U.S. Public Health Service guidelines for the management of occupational exposures to HIV and recommendations for postexposure</u>.

#### G. EMPLOYEE HEALTH AND IMMUNIZATION RECORDS

Employee occupational health records, including immunization records are maintained at one of the UW EHCs in a secure password-protected database.

#### H. SERUM BANKING AND MONITORING

Serum banking is the collection and frozen storage of serum samples obtained from employees who may be at risk for an occupationally acquired infection. Serum is the protein-rich liquid that separates out when blood changes to a solid or semisolid state (coagulates). The purpose of serum banking is to assess whether there was exposure to a research agent by providing the ability to compare serum obtained after an acute illness or exposure with serum obtained before the illness or potential exposure.



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As a standard practice, serum from research personnel will not be banked. However, specific serum collection and/or monitoring programs may be offered or required in some cases.

Determination of which biological agents include required or offered serum banking is made after review of the research protocols by the EH&S Biological Safety Program staff, EH&S EHC medical staff, and the University's Institutional Biosafety Committee (IBC), and in consultation with the principal investigator or supervisor. The University conducts serum banking only when: (1) it is required by federal regulations or suggested by evidence-based occupational health practice standards; and (2) there is a plan to analyze the data as part of a risk assessment strategy.

The University has three levels of serum banking requirement:

- 1. For work with most biological agents, serum banking is neither required nor offered.
- 2. For work with some biological agents (e.g., *Coxiella burnetti*), the UW Employee Health Center (EHC) must offer serum banking, but employees are not required to participate in order to work with those agents.
- 3. For work with a select few biological agents (e.g., highly pathogenic avian influenza virus), serum banking is required for all employees (research and support staff) who work with or may be exposed to the biological agent. University employees may not work in areas where these agents are in use unless they participate in serum banking.

See the <u>EH&S Serum Banking Policy</u> for research and support staff available online for more information. For questions, contact the EH&S OHN at 206-685-1026.



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## SECTION 6 – EMERGENCY PREPAREDNESS AND RESPONSE

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#### A. BIOHAZARDOUS SPILL CLEAN-UP PROCEDURES

This section provides spill clean-up procedures for BSL-1 and BSL-2 laboratories. These procedures apply to biohazardous agents and all recDNA. The <u>Spill Response Poster</u> provides instructions for spill response and must be posted in all laboratory and animal rooms where biohazards are used. Labs that operate at higher biosafety levels (i.e., BSL-2 with BSL-3 practices and BSL-3 laboratories) may have laboratory-specific spill clean-up procedures.

## 1. Responsibility

Each PI is responsible for developing spill clean-up procedures appropriate for the materials used in the laboratory, as well as assuring that a spill kit or spill clean-up materials are stored in an easily accessible location.

Furthermore, anyone working with biological materials must receive training in spill clean-up appropriate for the biological agents routinely used.

## 2. Biohazard Spill Kit

Assemble spill kit components in a single container that can be moved easily to a spill area. A large bucket is practical for the container as it can double as the secondary container for transporting waste away from the spill. Table 6-1 below lists biohazardous spill kit components.



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## 3. Spill Advice

For biohazardous spill advice contact EH&S ROS at 206-221-7770 during business hours (Monday thru Friday; 8:00 a.m. to 5:00 p.m.). Outside of business hours, call the UW Police Department at 206-685-UWPD to be directed to the EH&S staff on call.

**Table 6-1: Biohazardous Spill Kit Components** 

An appropriate chemical disinfectant	<ul> <li>A freshly prepared 1:10 dilution of household bleach, or</li> <li>Other decontaminant appropriate for agent in use</li> </ul>
Material to absorb liquids	<ul> <li>Paper towels,</li> <li>Absorbent lab pads, or</li> <li>Any other special materials designed to absorb large volumes of liquid</li> </ul>
Personal protective equipment (PPE)	<ul> <li>Nitrile or heavy duty gloves,</li> <li>Long-sleeved lab coat or gown,</li> <li>Safety glasses or goggles,</li> <li>Facial protection for large spills, and</li> <li>Any additional PPE required for agent</li> </ul>
A mechanical means to pick up broken glass	<ul> <li>Tongs,</li> <li>Forceps,</li> <li>Scoops,</li> <li>Sponges,</li> <li>Autoclavable dust pan, or</li> <li>Any other method that prevents direct contact with broken glass</li> </ul>
Containers for treatment and disposal	<ul> <li>Biohazard bags for clean-up waste,</li> <li>Sharps container for broken glass, and</li> <li>Plastic bucket or other secondary container for transport</li> </ul>
Printed spill clean-up instructions	Access biohazardous spill clean-up instructions for printing online at Biohazardous Spills.



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## 4. Immediate Response

Call 911 for any life-threatening emergency. The <u>Spill Response Poster</u> provides instructions for spill response and must be posted in all laboratory and animal rooms where biohazards are used. For a spill incident, follow these steps immediately:

## ENVIRONMENTAL HEALTH & SAFETY

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## SPILL RESPONSE



## **CALL 911 FOR ANY LIFE THREATENING EMERGENCY**

IF EXPOSED, FOLLOW THE EXPOSURE RESPONSE POSTER

## S.W.I.M. FOR ALL SPILLS

- **S: Stop** the spill. Cover with absorbent material.
- **W:** Warn others. Alert people in the immediate area of the spill.
  - **!: Isolate** the spill and secure the area. Close doors if possible.
- **M: Minimize** your exposure by wearing PPE and avoiding contact, inhalation or ingestion. Vacate the area if necessary. Wash hands after handling spill materials.

## RADIOLOGICAL SPILLS

- Utilize time, distance and shielding to prevent exposure.
- · Cover with absorbent material.
- Wear gloves and use tongs/scoop to collect contaminated material as radioactive waste.
- Call UW Radiation Safety at 206.543.0463. If office closed, call 911.
- · Notify your supervisor.

#### CHEMICAL SPILLS

- If exposed, use the eye wash or safety shower for 15 minutes.
- Large spills: Pull the fire alarm and evacuate. EH&S can arrange for hazardous spill cleanup at the lab's expense.
- Small spills: Trained personnel familiar with the chemical should use the lab's spill kit.
- Staff must protect themselves from skin, eye and respiratory hazards by using personal protective equipment (PPE) during cleanup.

#### EH&S chemical spill assistance is available 24/7:

- During business hours (Monday-Friday 8 a.m. to 5 p.m.), call **206.543.0467**.
- After business hours, call 206.685.UWPD (8973) to reach EH&S staff on call.

## **BIOHAZARDOUS SPILLS**

- Cover the spill with paper towels or absorbent material.
- Pour freshly prepared 10% bleach around the spill and allow to flow into spill.
- After 30 minutes of contact time, wipe up and dispose of as biohazard waste.
- · Repeat procedure.

If spill contains recombinant nucleic acids, notify EH&S Biosafety as soon as possible at **206.221.7770**.

Report all spills within 24 hours via UW OARS: https://oars.ehs.washington.edu

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#### 5. Biohazardous Spill Inside a Biological Safety Cabinet (BSC)

This section provides spill clean-up procedures for biohazardous agents and all recDNA inside a BSC. Printable biohazardous spill clean-up instructions are available online at <u>Biohazardous Spills</u>.

#### a. Spill inside a BSC that stays contained on the work surface

- 1. Do not turn off the BSC during spill clean-up. Do not place your head inside the cabinet or under the sash at any time.
- 2. Remove any sharp, contaminated objects from the spill area using mechanical means (like tongs or forceps) and never with hands. Discard contaminated sharps in a sturdy, leak-proof, biohazard labeled sharps container.
- 3. Cover the spill with paper towels or other absorbent material.
- 4. Slowly pour an appropriate decontaminant solution (Section 4.E) around the spill, and allow the solution to flow into the spill. Paper towels soaked with the decontaminant may also be used to cover the area. A freshly prepared 1:10 dilution of household bleach, (~0.5% sodium hypochlorite) is suitable for most biological spills.
- 5. Allow 30 minutes of contact time. The contact time may vary depending on the decontaminant used and the microbiological agent. Follow the manufacturer's directions.
- Wipe up the spill, work surfaces, walls, and any equipment in the cabinet with paper towels dampened with decontaminant. If using bleach, follow with a water rinse to protect metal surfaces from corrosion.
- 7. Place contaminated paper towels and other spill clean-up materials in a biohazard bag.
- 8. Decontaminate the spill area again. Place all used spill materials into a biohazard bag.
- 9. Remove any contaminated PPE in a manner to avoid cross-contamination; dispose of per standard lab practices.
- 10. Wash hands thoroughly after removing gloves.

#### b. Spill inside a BSC that flows into the front or rear grills

- 1. Do not turn off the BSC during spill clean-up. Do not place your head inside the cabinet or under the sash at any time.
- 2. Close the drain valve under the BSC if open.
- 3. Remove any sharp, contaminated objects from the spill area using mechanical means (like tongs or forceps) and never with hands. Discard contaminated sharps in a sturdy, leak-proof, biohazard labeled sharps container.
- 4. Flood the top work surface tray and, if a Class II BSC, the drain pans and catch basins below the work surface with a decontaminating solution that is appropriate for the agent involved (Section 4.E). A freshly prepared 1:10 dilution of household bleach, (approximately 0.5% sodium hypochlorite) is suitable for most biological spills.
- 5. Allow 30 minutes of contact time. The contact time may vary depending on the decontaminant used and the microbiological agent. Follow the manufacturer's directions.
- 6. Remove excess decontaminant from the work surface tray by wiping with a sponge or cloth. For Class II BSCs, drain the tray into the catch basin below the work surface,



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lift the tray and take out the removable front intake grille. Wipe the top and bottom (underside) surfaces of the grille with a sponge or cloth soaked in the decontaminant. Then place the tray in position, drain the decontaminant from the cabinet base into an appropriate container, and dispose of the decontaminant in the sewer.

- 7. Place contaminated paper towels and other clean-up materials in a biohazard bag.
- 8. Decontaminate the spill area again. Place all used spill materials into a biohazard bag.
- 9. Remove any contaminated PPE in a manner to avoid cross-contamination and dispose of per standard lab practices.
- 10. Wash hands thoroughly after removing gloves.

## 6. Biohazardous Spill Outside a BSC

#### a. Small spills that can easily be cleaned with one paper towel

- 1. If biological agent is transmitted via inhalation (e.g. adenovirus, influenza virus):
  - a. Hold your breath and leave the room immediately. Ask other lab occupants to also leave the room and close the door. One good way to identify the spill area is to drop your laboratory coat on the area on your way out.
  - b. Warn others not to enter the contaminated area and post a sign on the door.
  - c. Remove contaminated garments and put into a container for autoclaving.
  - d. Thoroughly wash any exposed areas of the body.
  - e. Wait 30 minutes for aerosols to dissipate.
- 2. Put on appropriate PPE (e.g., long-sleeve lab coat, goggles, and nitrile gloves).
- 3. Remove any sharp, contaminated objects from the spill area using mechanical means (e.g., tongs or forceps). Discard contaminated sharps in a sturdy, leak-proof, biohazard labeled sharps container.
- 4. Cover spill with paper towels or absorbent material.
- 5. Slowly pour an appropriate decontaminant solution (Section 4.G) around the spill, and allow the solution to flow into the spill. Paper towels soaked with the decontaminant may also be used to cover the area. A freshly prepared 1:10 dilution of household bleach, (approximately 0.5% sodium hypochlorite) is suitable for most biological spills. To avoid aerosolization, never pour decontaminant solution directly onto the spill.
- 6. Allow 30 minutes of contact time. The contact time may vary depending on the decontaminant used and the microbiological agent. Follow the manufacturer's directions
- 7. Wipe up the spill, work surfaces, walls, and any equipment in the cabinet with paper towels dampened with decontaminant. If using bleach, follow with a water rinse to protect metal surfaces from corrosion.
- 8. Place contaminated paper towels and other clean-up materials into a biohazard bag.
- 9. Decontaminate the spill area again. Place all used spill materials into a biohazard bag.
- 10. Remove any contaminated PPE in a manner to avoid cross contamination and dispose of per standard lab practices.
- 11. Wash hands thoroughly after removing gloves.



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#### b. Large spills that require more than one paper towel to absorb

- 1. Hold your breath and leave the room immediately. Close the door. Ask other lab occupants to also exit the room. A good way to indicate a spill is inside is to drop your laboratory coat on your way out.
- 2. Warn others not to enter the contaminated area and post a sign on the door.
- 3. Remove any contaminated PPE and place in a biohazard bag for autoclaving.
- 4. Thoroughly wash your hands and any exposed areas of the body.
- 5. Wait 30 minutes for aerosols to dissipate.
- 6. Assemble spill clean-up materials.
- 7. Put on appropriate PPE (e.g., long-sleeve gown, goggles, and nitrile or heavy duty gloves) before re-entering the room.
- 8. Remove any sharp, contaminated objects from the spill area using mechanical means (e.g., tongs or forceps). Discard contaminated sharps in a sturdy, leak-proof, biohazard labeled sharps container.
- 9. Slowly pour an appropriate decontaminant solution (Section 4.E) around the spill, and allow the solution to flow into the spill. Paper towels soaked with the decontaminant may also be used to cover the area. A freshly prepared 1:10 dilution of household bleach, (approximately 0.5% sodium hypochlorite) is suitable for most biological spills. To avoid aerosolization, never pour decontaminant solution directly onto the spill.
- Allow 30 minutes of contact time. The contact time may vary depending on the decontaminant used and the microbiological agent. Follow the manufacturer's directions.
- 11. Remove excess decontaminant by wiping with a sponge or several paper towels. Place contaminated clean-up materials in a biohazard bag.
- 12. Decontaminate the spill area again. Place all used spill materials into a biohazard bag.
- 13. Remove any contaminated PPE in a manner to avoid cross-contamination and dispose of per standard lab practices.
- 14. Wash hands thoroughly after removing gloves.

## 7. Spills Outside the Laboratory in Public Spaces

Transport biohazardous materials in secondary, leak-proof containers to minimize the potential for spills. Use a cart if necessary. If a spill does occur in a common hallway or public space, cordon off the area, restrict access, and decontaminate the spill with appropriate disinfectant. If the spill cannot be immediately decontaminated, contact EH&S ROS at 206-221-7770.

#### 8. Radioactive Biohazardous Spill

Anyone working with both radioactive and biohazardous materials should develop a spill clean-up plan appropriate for all materials used. Some general principles should apply: a) contain the spill, b) prevent spreading the contamination, and c) choose methods for decontamination that do not create "mixed waste". Decontamination procedures involving the use of bleach may be incompatible with some radioactive materials, especially those containing radioiodine. Contact EH&S Radiation Safety at 206-543-0463 for additional information concerning these materials.



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## **B. INJURY POLICY AND ACCIDENT REPORTING**

## 1. Injury Policy

An exposure incident is defined as a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with biohazardous agents, which includes all recDNA. Examples of exposure incidents include needlesticks, splash/splatter to the mucous membranes of the face, and any other incident that involves contact between blood or OPIM and non-intact skin (cuts, scratches, chapped skin, etc.). This policy applies to all students, faculty, and staff of the UW.

If the injury/accident involves a potential exposure to a biohazardous agent, including all recDNA, initiate the steps in Section 4.B.2 below immediately. Call 911 for any life-threatening emergency. If an injury exposure involves significant personal exposure to recDNA, EH&S may need to notify the NIH.



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## 2. Immediate Response

Call 911 for any life-threatening emergency. The Exposure Response Poster provides instructions for exposure response and should be posted in all laboratory areas. For an exposure incident, follow these steps immediately:

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## EXPOSURE RESPONSE



for biological, chemical, or radiological exposures

## CALL 911 FOR ANY LIFE THREATENING EMERGENCY

#### 1. PERFORM FIRST AID

injury, or animal bite/scratch sudsing soap.

Needlestick, puncture or sharps Wash thoroughly for 15 minutes with warm water and

Eye exposure Use emergency station to flush eyes for 15 minutes while holding eyes open.

Skin exposure •

- Radioactive: Survey skin and wash until the count rate cannot be reduced further. Stop if skin becomes irritated.
- Chemical: Wash with tepid water for 15 minutes.
- · Hydrofluoric acid: Wash for 5 minutes, then apply calcium gluconate gel to skin.
- Biological: Wash with sudsing soap and water for 15 minutes.

Inhalation or ingestion •

- Move out of the contaminated area and seek fresh air.
- Do not induce vomiting unless instructed to do so.
- Radioactive: Blow nose into clean tissue and survey for contamination.

#### 2. GET MEDICAL HELP

- For radiological exposure Call Radiation Safety at 206-543-0463.

  - or emergency: Call 911 if office closed.
    - Provide the radionuclide, estimated amount and time since exposure.

  - For chemical exposure · Call 911 and follow the instructions given.

    - or emergency: . Provide the chemical name, concentration, time since exposure and Safety Data Sheet (SDS).
- For biological and Call the Employee Health Center at 206-685-1026.
  - all other exposures: Harborview sites call 206-744-3081.
    - If closed, call 911 and follow the instructions given.
    - For all exposures: Notify your supervisor.
- - Secure the area before leaving.

#### 3. REPORT THE INCIDENT

or recombinant nucleic acid medical help:

For hospitalization, fatality, Notify EH&S immediately after performing first aid and getting

- exposure: Call the EH&S main phone line at 206-543-7262.
  - If closed, call 206-685-UWPD(8973) to reach EH&S staff on call.

All incidents and near misses: Submit a report via the UW Online Accident Report (OARS) within 24 hours at https://oars.ehs.washington.edu.

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- For injuries or exposures involving animals, immediately stop work and follow the steps outlined above. If working with animals exposed to biohazards, follow the specific Department of Comparative Medicine procedures. If the exposure occurs outside of a Comparative Medicine vivarium, be prepared to share information to with medical providers about any agents the animals may have been experimentally exposed to.
- **For injuries or exposures involving non-human primates,** follow the WaNPRC specific response procedures. Follow the instructions in the provided B virus exposure kit for first aid. Contact the WaNPRC at 206-543-8686 for additional information about non-human primate exposure procedures.
- **For exposures from animals that previously received recDNA**, notify EH&S Research and Occupational Safety as soon as possible at 206-221-7770.

## 3. Accident Reporting

The <u>UW Administrative Policy Statement 10.8</u> requires that any accident, injury, work-related illness, or on-the-job incident that could have caused an injury/illness must be reported to EH&S.

The exposed worker or the PI/lab manager must complete the on-line accident/incident report within 24 hours of the occurrence by using the OARS. If the accident/incident involves recDNA, this must be noted in the description of the incident.

In the case of a serious or fatal accident or hospitalization, notify EH&S immediately (within eight hours) at 206 543-7262; after hours, contact the UW Police Department at 206-685-UWPD.

Both the Washington State Department of Labor and Industries and OSHA require employers to record work related injuries and illnesses. Both of these regulations and the Health Insurance Portability and Accountability Act (HIPAA) rules expressly permit disclosure of this protected information (45 CFR 164.512). UW employees having access to this report must treat it as private and should not disclose it to others unless authorized by statute. An employee may not be discriminated against for reporting a work-related fatality, injury, or illness.



# APPENDIX A – BLOODBORNE PATHOGENS EXPOSURE CONTROL PLAN

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#### A. INTRODUCTION

This section serves as the UW Core Bloodborne Pathogens Exposure Control Plan (ECP) and describes the requirements of the UW BBP Program. The purpose of the Program is to help ensure occupational health and safety and meet compliance with the Washington State BBP Rule, WAC 296-823. This rule applies to all occupational exposure to human blood or other potentially infectious materials. It requires employers to identify potential for occupational exposures and implement methods to mitigate these exposures through a variety of methods.

This core ECP was developed with research and clinical laboratories in mind. More specific information for patient care is available from Infection Control at UW Medicine Academic Medical Centers, i.e. University of Washington Medical Center, Montlake and Northwest, Harborview Medical Center, and Valley Medical Center; UW Schools of Medicine and Dentistry, including associated UW Clinics; UW Airlift Northwest; and other UW Medicine groups and affiliates such as Seattle Cancer Care Alliance. Persons at clinical patient care sites are directed to their respective departments for more information on training and requirements.

#### **B. ROLES AND RESPONSIBILITIES**

#### 1. Principal Investigator/Supervisor

The PI or Unit Manager is responsible for identifying employees who need to be in the BBP program and has ultimate responsibility for ensuring that safety rules and requirements of the BBP Program are followed.

The PI (or their designee), or the Unit Manager must develop and implement a Site-Specific BBP ECP and the EH&S template Site-Specific BBP ECP Form can be used for this purpose. It must include information about who is in the BBP program, controls used to mitigate BBP exposure, personal protective equipment required for tasks, decontamination procedures, and first aid and medical response in case of exposure. The Site-Specific BBP ECP must be reviewed annually and updated as necessary. It should be used in conjunction with this core ECP.

#### 2. Employee

The employee is responsible for following the Site-Specific BBP ECP. All practices must be adhered to, including wearing required PPE. The employee is responsible to ask questions if needed and to make suggestions to the PI/supervisor for safer work practices and procedures.

#### 3. Employee Health Center

The Employee Health Center provides clinical services and administers the hepatitis B vaccine. The EHC also provides post-exposure counseling and medical follow-up.

#### 4. Environmental Health and Safety Department

EH&S administers the UW BBP Program. This includes maintaining the UW Core BBP Exposure Control Plan, assisting employees in obtaining the hepatitis B vaccine, providing BBP training, maintaining the injury log, providing consultation, and developing compliance tools to assist PIs/supervisors.



#### C. EXPOSURE DETERMINATION

BBP are pathogenic microorganisms that are present in human blood and OPIM that can cause disease. All UW employees with reasonably anticipated potential for exposure to human blood and its components, human tissue, all human cell lines, human source materials, as well as medications derived from blood (e.g., immunoglobulins, albumin), and OPIM are required to comply with the University's BBP Program. OPIM includes all of the following:

- Human cells (including all primary and established human cell lines), human tissue or human organ cultures
- Culture supernatant
- Pericardial fluid
- Synovial fluid
- Pleural fluid
- Any solutions containing HIV, HBV, HCV, or other BBP
- Any body fluid visibly contaminated with blood or OPIM
- Saliva during dental procedures
- Peritoneal fluid
- Vaginal secretions
- Amniotic fluid
- Semen
- Any unfixed tissue or organ (other than intact skin) from a human (living or dead)
- Blood, organs, or tissues from animals infected with HIV, HBV, HCV, or other BBP
- Any fluid where it is difficult to identify the presence or absence of blood

Urine, feces, vomit, sweat, tears, and saliva are not regulated under the BBP rule because they are not considered to present a risk for BBP transmission unless there is visible blood in them. However, they should still be approached with caution; personnel should use protective (nitrile) gloves and/or other PPE as needed when handling.

PIs/supervisors are responsible for assessing activities in the workplace, determining if employees have a potential for occupational exposure, and documenting the risk in the Site-Specific BBP ECP.

Individual exposure determinations must be made for existing workers on an on-going basis and prior to assigning or reassigning workers to job classifications with potential for exposure. The exposure determination must be made without regard to the use of PPE. Listed below are examples of tasks that involve potential exposure to blood or OPIM.

- Cleaning up a blood/body fluid spill or handling contaminated waste or laundry;
- Culturing and/or propagating human cells, viruses, including all human and SIV/SHIV nonhuman primate retroviruses in laboratory culture and experimental animals.
- Removing, preparing, and/or storing any unfixed tissue or organ from a human;
- Providing patient care in a clinical or research setting;
- Providing emergency services or functions in public safety where delivery of trauma care is likely, i.e., lifeguards, police officers, fire fighters, etc.



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#### D. UNIVERSAL PRECAUTIONS

Universal Precautions is an approach to protecting humans through infection prevention activities. This approach requires that all human blood, body fluids, and OPIM be treated as if they are known to be infectious for BBP. Engineering controls, work practices, and PPE shall be used to prevent contact with human blood and OPIM. Under circumstances in which differentiation between body fluid types is difficult or impossible, all human body fluids should be considered OPIM.

#### E. ENGINEERING/WORK PRACTICE CONTROLS

#### 1. Engineering Controls

Engineering controls serve to reduce worker exposure either by removing the hazard or by isolating the worker from exposure. Examples are:

- Protective splash/splatter shields
- Needles with safety features (e.g., self-sheathing needles, retractable needles)
- Capture ventilation
- Biological safety cabinets
- Air filters
- Ventilated equipment
- Sharps disposal containers
- Enclosures

## 2. Hand Hygiene

Hand hygiene facilities must be available. If a sink with warm running water is not immediately available, a 60-95% alcohol-based gel hand sanitizer should be used until the employee can wash hands in a sink.

Employees should immediately wash hands with soap and water upon glove removal and on completion of tasks involving contact with human blood, body fluids, or OPIM.

#### 3. Sharps

BBP exposures occur readily from needlestick or sharps injury to the skin. See the <u>Sharps Safety</u> in <u>Research PDF</u> for more information about working safely with needles and sharp items during research.

Preventative sharps safety practices are listed below:

- a. Needles must not be recapped, purposely bent or broken, removed from disposable syringes, or otherwise manipulated. If recapping a syringe is unavoidable, then a safe procedure for doing this must be followed (one-hand scoop method) preferably using a recapping device. Ideally syringe preparation and injection should occur at the same location;
- b. Sharps are not to be placed in the regular trash, and must be disposed of immediately or as soon as possible after use.



- c. Needles with safety features should be used whenever possible; information and products can be found online at the International Sharps Prevention website or EH&S Sharps Safety webpage.
- d. Needles or sharps of any kind shall not be left on the work surface. Instead, a syringe holder or magnetic strip can be used to hold razor blades.
- e. Procedures for proper restraint of animals must be ensured during injections. If necessary more than one person should assist.
- f. After use, needles and disposable scalpel blades, lancets, and other contaminated sharp items (i.e., broken glass, razor blades, fragile glass items, glass slides and cover slips) must be placed in puncture-resistant sharps containers for disposal.
- g. Place contaminated reusable sharps immediately, or as soon as possible after use, in appropriate sharps containers until properly decontaminated. For additional information on sharps disposal, see the <a href="EH&S Sharps and Lab Glass Disposal">EH&S Sharps and Lab Glass Disposal</a> webpage.
- h. Broken glassware is not handled directly. Instead, it is removed using a brush and dustpan, tongs, or forceps.

#### 4. Eating, Drinking, and Smoking

Eating, drinking, smoking, and other activities including applying cosmetics or lip balm, handling contact lenses, placing any article in the mouth, eyes, or nose, or other contact with mucous membranes is prohibited in work areas where there is a likelihood of occupational exposure to blood or OPIM.

Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets, or on countertops or bench tops where blood or OPIM are stored or used.

## 5. Mouth Pipetting/Suctioning

To prevent accidental ingestion of potentially infectious materials, mouth pipetting or suctioning is strictly prohibited.

#### 6. Aerosols

All procedures involving blood or OPIM shall be performed in such a manner as to minimize splashing, spraying, splattering, or generation of droplets of these substances. Such activity should be conducted in a certified BSC.

#### 7. Centrifuging

Containment devices such as centrifuge safety cups and sealed rotors are recommended to protect the worker from exposure to microbial aerosols and droplets. Safety characteristics of centrifuges are only effective if the equipment is operated properly, thus training in the correct use of the equipment and routine inspections, with regular re-certification of the centrifuge are essential. See Section 4.D.7.

#### 8. Transporting and Shipping Biohazardous Materials

Specimen containers used for blood or OPIM must be leak-proof. They also need to be red in color or labeled with the biohazard symbol. Anytime specimens of blood or OPIM are transported within the building or between buildings, the specimen container must be placed inside a secondary container that is also leak-proof, providing a double barrier. Additional



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information on transporting biohazardous materials is found on the EH&S Biohazardous Wastepage.

All specimens of blood or OPIM must be properly packaged for shipment by mail or courier service. Information on packaging and shipping hazardous materials is available on the <a href="EH&S">EH&S</a> Shipping Hazardous Materials page. Training on the shipping of Hazardous Materials is required; and personnel must be re-certified every two years. For questions, contact EH&S Environmental Programs at 206-616-5835.

## 9. Equipment Servicing and Maintenance

Equipment that may be contaminated with blood or OPIM must be decontaminated prior to servicing. Equipment being repaired, surplused, or disposed of must be decontaminated. A Notice of Laboratory Equipment Decontamination must be completed to certify that this has been done. The notice of decontamination form has information on how to decontaminate various types of equipment and who to call for guestions.

When a portion of the equipment cannot be decontaminated, the equipment must be labeled with the biohazard label as well as stating which portion of the equipment remains contaminated. This information must be conveyed to all repair workers and servicing representatives and/or the manufacturer as necessary prior to handling, servicing, or shipping so that appropriate precautions will be taken.

## F. PERSONAL PROTECTIVE EQUIPMENT

## 1. Requirements

The PI/supervisor must ensure that PPE for identified hazards is readily available in appropriate sizes at the worksite or is issued to the worker. The PI/supervisor is responsible for ensuring that a PPE hazard assessment is completed, that required PPE is documented in the Site-Specific BBP Exposure Control Plan, and that it is worn correctly by staff. Required PPE must be provided at no cost to employees. Refer to the <a href="EH&S PPE page">EH&S PPE page</a> and to the PPE information in Section 4.B.4.

PPE includes but is not limited to gloves, gowns, laboratory coats, clinic jackets, aprons, face shields or masks, eye protection (goggles, safety glasses with side shields) mouthpieces, resuscitation bags, and pocket masks or other ventilation devices. Surgical caps or hoods and shoe coverings or boots shall be worn in instances when gross contamination can be anticipated.

In order to be effective, PPE must prevent blood or OPIM from soaking through to the user's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membrane under normal conditions of use and for the duration of time for which the PPE will be used.

PPE must be cleaned, laundered, or disposed of and repaired or replaced as needed to maintain its effectiveness. See #5 below.

#### 2. Gloves

Appropriate gloves (latex or nitrile) must be provided to and worn by workers when handling blood or OPIM. Hypoallergenic gloves, glove liners, powderless gloves, or other similar alternatives are recommended to prevent allergies to latex.



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Double gloves may appropriately be used by persons with dermatitis, skin breaks, or as needed when working directly with biohazardous agents. Replace disposable gloves when contaminated, torn, punctured, or when their ability to function as a barrier is compromised. Do not wash or decontaminate disposable gloves for reuse.

Wear nitrile or other chemically resistant gloves when working with chemicals. Latex gloves do not provide adequate chemical protection.

#### 3. Face Protection

Moisture resistant surgical face masks in combination with eye protection devices such as goggles, close fitting glasses with solid side shields, or chin-length face shields must be worn whenever splashes, spray, splatter, droplets of blood, or OPIM may be generated and where eye, nose, or mouth contamination can be anticipated. A table-top plexiglas® shield can provide additional protection from splash/splatter when work is performed behind the shield. Respirators are not typically required for work with BBP unless aerosol-generating activities are performed outside of a containment device. If these activities are anticipated, contact EH&S at 206-221-7770 for consultation about the potential need for respirators.

#### 4. Use and Removal

The PI/supervisor must ensure that employees use appropriate PPE when performing tasks with identified hazards. The types of PPE worn will depend upon the sort of work being done and the exposure anticipated. PPE must be removed and discarded carefully to prevent cross contamination. Hands must be washed after removal of PPE and any time they may be contaminated.

## 5. Cleaning, Laundering or Disposal

The decontamination and disposal of single use PPE shall be in accordance with established University procedures for the treatment and disposal of biohazardous waste as described on the EH&S Biohazardous Waste page.

It shall be the responsibility of the PI/supervisor to ensure that laundry service for personal protective clothing is provided. Workers must not launder any personal protective clothing in their homes; the employer or contractor provides this service.

All laundry shall be handled using Universal Precautions. If the contaminated laundry is wet and presents a reasonable likelihood of leakage, it must be double-bagged in plastic or other leak-proof bags.

#### **G. WORKSITE CONDITIONS**

#### 1. Responsibility

It is the responsibility of the PI/supervisor to ensure that the worksite is maintained in a clean and sanitary condition. Decontamination procedures can be found on the <a href="EH&S Biohazardous">EH&S Biohazardous</a> Waste page.

#### 2. Spill Clean-up

All workers must be familiar with procedures for decontamination and clean-up of spills of blood and potentially infectious materials. It is recommended that the use of glass be avoided



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whenever possible when working with biohazards since sharp broken glass can add another hazard.

Each laboratory shall have a specific procedure for dealing with spill cleanup based on the type and quantity of blood or OPIM handled, as well as the surfaces to be decontaminated. In addition to the procedure, cleanup supplies must be readily available. At a minimum, these supplies should include suitable disinfectants, gloves, paper towels or other absorbent material, forceps or tongs for broken glass or other sharps, an autoclavable squeegee and dust pan, and autoclave bags or other disposal container. Additional information on spill clean-up is found online in Biohazardous Spills.

## 3. Cleaning Schedule

All floors, laboratory benches, and other surfaces shall be chemically decontaminated as often as deemed necessary by the PI/supervisor. The chemical decontaminant used is at the discretion of the PI/supervisor but must either be an EPA-registered tuberculocidal (List B), sterilant (List A), or a product registered against HIV/HBV (List D).

At a minimum, work surfaces are decontaminated at least daily, immediately after contamination with blood or OPIM, or following a spill.

At a minimum, floors shall be wet mopped on a weekly basis. Spills on the floor are decontaminated and cleaned up promptly.

## 4. Protective Coverings

When protective coverings such as plastic or aluminum wrap or absorbent pads are used, these coverings should be removed and replaced either when visibly contaminated or at the end of the work shift (if contamination was likely during the shift).

#### 5. Biohazardous Waste

All untreated biohazardous waste must be handled using Universal Precautions. Disposable sharps containers must not be reused and must be autoclaved prior to disposal. Additional information on biohazardous waste treatment and disposal is found on the <a href="EH&S Biohazardous">EH&S Biohazardous</a> Waste page including flowcharts describing where and how to dispose of waste for your location.

Reusable waste receptacles for biohazardous waste shall be decontaminated each time they are emptied. Alternatively, the receptacle can be protected from contamination by a disposable liner (in addition to the biohazard waste bag) that shall be removed at the same time as the removal of the waste. The liner should be handled as biohazardous waste.

Broken contaminated glassware too large to fit into a 5-gallon sharps container shall be transported and treated in an autoclave-resistant plastic bin and then packaged and disposed of as laboratory glass as described on the <u>EH&S Sharps and Laboratory Glass page</u>.

Other biohazardous waste that does not pose the threat of skin puncture shall be placed in plastic biohazard bags. A leak-proof second container is required while transporting to the autoclave for treatment. If this container covers the biohazard label on the bag, the outer container must have the biohazard label. This secondary container shall be autoclaved or otherwise decontaminated prior to reuse.



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If biohazardous waste is to be shipped off-site for treatment via a contracted carrier, packaging must be done in accordance with the Department of Transportation (DOT) requirements. Any faculty or staff who will perform the final packaging steps and offer shipments must complete the EH&S training before setting up an account with the waste contractor.

#### H. BIOHAZARD SIGNS AND LABELS

The <u>Biohazard Warning Sign</u> must be used to restrict laboratory access when work with biohazardous materials is taking place, to communicate agents in use, and to specify entry and exit requirements. The sign includes the universal biohazard symbol which is required to have the fluorescent orange background with the symbol and lettering in a contrasting color.

Biohazard warning labels shall either be an integral part of the container or shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.

Warning labels must be affixed to containers of biohazardous waste, refrigerators and freezers containing blood or OPIM, and other containers used to store, transport, mail, or ship blood or OPIM. See the <a href="EH&S Biological Research Safety page">EH&S Biological Research Safety page</a>.

Biohazard labels do not need to be used on the following:

- Red bags or red containers when the color red is recognized as meaning the same as the warning label, or
- Containers of blood, blood components, or blood products that are labeled as to their contents and have been released for transfusion or other clinical use, or
- Individual containers of blood or OPIM that are placed in a labeled container during storage, transport, shipment, or disposal.

#### I. HEPATITIS B IMMUNIZATION

#### 1. Offering Hepatitis B Vaccine

The PI/supervisor must assure that all workers with the potential for occupational exposure to BBP are offered the hepatitis B vaccine at no cost to the worker within ten days from the start of the work assignment and after receiving BBP training. For all employees who are in the UW BBP program, the Hepatitis B Vaccine Form is required to be completed in order to ensure this vaccine is offered.

The Hepatitis B Vaccine Form is offered via the online BBP training course, and is required prior to work with a potential for exposure to human blood and OPIM. Information is given on the efficacy, safety, method of administration, and the benefits of the hepatitis B vaccine. The form asks for hepatitis B vaccine dates if the employee has received the vaccination in the past. The completed form is forwarded to the Employee Health Center for review and follow-up.

Employees who decline immunization must sign and date a waiver section on the Hepatitis B Form after reading the waiver statement indicating an understanding of the risks of declining the vaccine. The decision to refuse the vaccination can be reversed at any time without penalty to the employee, by contacting the Employee Health Center.

After receipt of the Hepatitis B Form, the EHCmay ask for verification of immunization for workers previously immunized.



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Prescreening of workers (pre-vaccine blood titers) shall not be a condition for beginning the hepatitis B immunization series. However, a post vaccine antibody titer (Anti-HBs) may be recommended to assure the efficacy of the immunization.

For questions about the Hepatitis B immunization, contact Employee Health (206-685-1026).

## 2. Administering Hepatitis B Vaccine

University staff and faculty are responsible for contacting the EHC and scheduling an appointment to receive the hepatitis B vaccine. Hepatitis B immunization is given as recommended by the U.S. Public Health Service. Booster immunizations are not recommended at this time. If a need for booster immunization is demonstrated in the future, these immunizations will be offered. More information about hepatitis B vaccine can be found on the CDC website.

## J. POST-EXPOSURE REQUIREMENTS

## 1. Exposure Incident

An exposure incident is defined as specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with human blood or OPIM. Examples of exposure incidents include needlesticks, splash/spatter to the mucous membranes of the face, and any other incident that involves contact between blood or OPIM and non-intact skin (cuts, scratches, chapped skin, etc.).

#### 2. Immediate Response

Following an exposure incident, complete the following steps as on Figure A-1, the <u>EH&S</u> <u>Exposure Response Poster</u>. This poster should be printed and posted in work area for quick reference.



Figure A-1: Exposure Response Poster

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## EXPOSURE RESPONSE



for biological, chemical, or radiological exposures

## CALL 911 FOR ANY LIFE THREATENING EMERGENCY

## 1. PERFORM FIRST AID

injury, or animal bite/scratch sudsing soap.

Needlestick, puncture or sharps Wash thoroughly for 15 minutes with warm water and

Eye exposure Use emergency station to flush eyes for 15 minutes while holding eyes open.

Skin exposure •

- Radioactive: Survey skin and wash until the count rate cannot be reduced further. Stop if skin becomes irritated.
- Chemical: Wash with tepid water for 15 minutes.
- · Hydrofluoric acid: Wash for 5 minutes, then apply calcium gluconate gel to skin.
- Biological: Wash with sudsing soap and water for 15 minutes.

- Inhalation or ingestion Move out of the contaminated area and seek fresh air.
  - Do not induce vomiting unless instructed to do so.
  - · Radioactive: Blow nose into clean tissue and survey for contamination.

## 2. GET MEDICAL HELP

- For radiological exposure Call Radiation Safety at 206-543-0463.
  - or emergency: Call 911 if office closed.
    - · Provide the radionuclide, estimated amount and time since exposure.

- For chemical exposure Call 911 and follow the instructions given.

  - or emergency: Provide the chemical name, concentration, time since exposure and Safety Data Sheet (SDS).

- For biological and Call the Employee Health Center at 206-685-1026.
- all other exposures: Harborview sites call 206-744-3081.
  - · If closed, call 911 and follow the instructions given.

- For all exposures: Notify your supervisor.
  - · Secure the area before leaving.

## 3. REPORT THE INCIDENT

or recombinant nucleic acid medical help:

For hospitalization, fatality, Notify EH&S immediately after performing first aid and getting

- exposure: Call the EH&S main phone line at 206-543-7262.
  - If closed, call 206-685-UWPD(8973) to reach EH&S staff on call.

All incidents and near misses: Submit a report via the UW Online Accident Report (OARS) within 24 hours at <a href="https://oars.ehs.washington.edu">https://oars.ehs.washington.edu</a>.

September 2019

www.ehs.washington.edu



## 3. Principal Investigator/Supervisor Responsibility

The PI/supervisor is responsible for assisting the exposed worker in seeking the necessary and immediate medical evaluation and consultation following an exposure incident. The following table is provided to assist the PI/supervisor in obtaining immediate medical consultation and evaluation for an exposed worker.

**Table A-2: Medical Referral Guide** 

Worker's Location	Department	Phone
University of Washington including South Lake Union and WaNPRC Facilities	Employee Health Center (EHC) at Hall Health	206-685-1026
UW Medical Center- Montlake	EHC at UWMC - Montlake	206-598-4848
UW Medical Center- Northwest	EHC at UWMC - Northwest	206-668-1625
Harborview Medical Center	Employee Health Services	206-744-3081
Valley Medical Center	Employee Health	425-690-3674
UW Neighborhood Clinics	Employee Health	206.520.5536
Other affiliate site:	Clinic to call for injury:	Phone of clinic:

#### 4. Evaluation Post Exposure

The worker who has had a potential BBP exposure will receive a copy of WAC 296-823 describing their rights and a post-exposure medical evaluation and follow-up as described in this section below.

- a. A medical evaluation will be performed immediately after exposure and will be all of the following:
  - Confidential,
  - At no cost to employee,
  - At a reasonable time and place, and
  - Administered by a licensed physician or HCP.
- b. The examination will include at least these elements:
  - 1) Documentation of the routes of exposure and the circumstances under which the exposure happened



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- 2) Identification and documentation of the source (individual or materials) if possible
- 3) Serial collection and testing of blood to detect the presence of HIV and/or HBV; in the event the worker does not permit serologic testing, a baseline blood sample will be held for at least 90 days
- 4) Post-exposure treatment when medically indicated and as recommended by the U.S. Public Health Service
- 5) Counseling about the results of testing and information regarding state laws concerning disclosure of the information
- 6) Evaluation of reported illnesses subsequent to the exposure
- c. The treating healthcare provider (HCP) is to provide the employee with a copy of the written opinion on the post-exposure evaluation within 15 days of the incident. This written opinion includes whether Hepatitis B vaccination is indicated for the employee and if the employee has received such vaccination. It documents that a medical evaluation took place following the exposure incident, that the employee has been informed of the results of the evaluation, and that the employee has been counseled about potential medical conditions resulting from exposure to blood or OPIM that may need further evaluation or treatment. All other findings are to remain confidential.

It is the responsibility of the PI/supervisor to assist the employee in obtaining a copy of the report if it has not already been provided to the employee. The employee should tell their supervisor if a copy of this report has not been received within 15 days.

#### K. TRAINING PROGRAM

## 1. Responsibility

PI/supervisor must ensure that staff complete <u>BBP training</u>. Training must follow standards set forth in WAC 296-823. Training for all employees who have the potential for occupational exposure to human blood or OPIM must be the following:

- Provided at no cost to the employee
- Required prior to work with these materials, and within one year of the previous training
- To take place during compensated work hours

EH&S offers online BBP training. For research laboratories, verification of current EH&S BBP training is required prior to approval from the Institutional Biosafety Committee.

Departments/supervisors who choose to provide their own BBP training must first consult with EH&S (206-221-7770) to ensure the training meets the requirements set forth in the BBP Rule.

In addition to EH&S BBP training, PIs/supervisors must provide additional documented training to their staff on the Site-Specific BBP Exposure Control Plan prior to work, annually, and when there are changes such as new or modified tasks or procedures that may affect exposure potential.



## 2. Training Requirements

The training program must contain the following elements:

- a. An accessible copy of the regulatory text of the bloodborne standard and an explanation of its contents;
- b. A general explanation of the epidemiology and symptoms of bloodborne diseases;
- c. An explanation of the modes of transmission of bloodborne pathogens;
- d. An explanation of the UW's ECP and the means by which the worker can obtain a copy of the written plan;
- e. An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and OPIM;
- f. An explanation of the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, work practices, and PPE;
- g. An explanation of the basis for selection of PPE, as well as information on the types, proper use, location, removal, handling, decontamination, and disposal of personal protective equipment;
- h. Information on the Hepatitis B vaccine, including information on its efficacy, safety, method of administration, benefits of being vaccinated, and that the vaccine and immunization will be offered free of charge;
- i. Information on the appropriate actions to take and persons to contact in an emergency involving blood or OPIM;
- j. An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow up that will be made available;
- k. Information on the post-exposure evaluation and follow up that the PI is required to provide for the worker following an exposure incident;
- I. An explanation of the signs and labels and/or color coding as required and used; and
- m. An opportunity for interactive questions and answers with the person conducting the training session.

#### L. RECORDKEEPING

#### 1. Medical Records

The treating facility will establish and maintain accurate and confidential records for each worker with occupational exposure for at least the duration of employment plus thirty years in accordance with WAC 296-823-170.

At a minimum the record shall contain:

- Worker name
- A copy of the written opinion sent to the employee following evaluation for Hepatitis B immunization as well as the worker's Hepatitis B immunization status and any other medical records relative to the worker's ability to receive the immunization. In lieu of



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this, the file will have the declination form signed by the worker declining the Hepatitis B immunization

- The results of examination, medical testing, and follow-up procedures following an exposure incident
- A copy of the written opinion sent to the PI/supervisor following a post-exposure medical evaluation
- A copy of the information provided by the Pl/supervisor following an exposure incident

## 2. Training Records

EH&S tracks all employee attendance for training conducted by EH&S. These records are kept for at least three years after the date on which the training occurred. PIs/supervisors must also maintain records of site-specific laboratory training conducted by the laboratory and/or department.

Training records must contain:

- The date(s) and location(s) of the training
- A summary of the training course content
- The names and qualifications of the instructors
- The names of all persons attending the training

## 3. Availability

All records described shall be made available for examination and copying to the Director of the Washington State Department of Labor and Industries.

Medical records will be available for examination and copying to the worker or any person with the worker's written consent.

Training records will be available for examination and copying to workers or employee representatives.

#### M. ACCESSIBILITY OF THE ECP

Each PI/supervisor is responsible for ensuring that laboratory staff and workers can access and consult the Site-Specific BBP ECP at any time.

A copy of the exposure plan must be available to the Director of the Washington State Department of Labor and Industries upon request for examination and copying.

#### N. ANNUAL UPDATE OF THE ECP

The lab's Site-Specific BBP ECP will be reviewed and updated when necessary and at least annually.

The PI/supervisor is responsible for reviewing the lab's Site-Specific BBP ECP annually and whenever necessary to reflect new or modified tasks and procedures that affect the potential for occupational exposure and to reflect new or revised worker positions with the potential for occupational exposure.



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# O. ADDITIONAL REQUIREMENTS FOR HIV, HBV, AND HCV RESEARCH LABORATORIES

## 1. Application

This section applies to a research laboratory engaged in the culture, production, concentration, and manipulation of HIV, HBV, and HCV. It also applies to work with SIV/SHIV non-human primate retroviruses. Such a facility works with high titer concentrations of virus but not with volumes greater than one liter. These requirements apply in addition to the other requirements of the ECP. If greater volumes are used the facility is called an HIV/HBV/HCV Production facility.

This section does not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissues, or organs.

In addition to the above, research involving the culture and/or production of HIV, HBV, or HCV must be reviewed and approved by the IBC before the activities can commence. This review will include a determination as to the appropriate biosafety level and practices, which are typically elevated for research with these agents.

## 2. Facility Requirements

Each laboratory shall contain a facility for hand washing and an eyewash facility that is readily available within the work area. The sink shall be foot, elbow, or automatically operated and located near the exit door.

An autoclave for decontamination of regulated waste shall be available. Refer to the location-specific <u>Biohazardous Waste Flow Charts</u> for decontamination and disposal of these materials at your location.

Vacuum lines are to be protected with liquid disinfectant traps and HEPA filters or filters of equivalent or superior efficiency. Traps and filters must be checked routinely and maintained or replaced as necessary.

## 3. Access Policy

Access to the work area is to be limited to authorized persons. Written policies and procedures shall be established whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements, and who comply with all entry and exit procedures before being allowed to enter the work areas and animal rooms.

Laboratory doors are to be kept closed when work involving HIV, HBV, or HCV is in progress. The PI/supervisor must post biohazard signs on all access doors. For more information on biohazard signs, refer to the <u>EH&S Biological Research Safety page</u>.

#### 4. Biosafety Manual

The lab-specific BSL 2 with BSL-3 practices Biosafety Manual (BSL2 w/3 practices BSM) must be available in the laboratory in hard copy form or as an obvious icon/shortcut on a laboratory computer that is accessible to lab members. Personnel must be advised of potential hazards and are required to read and implement the instructions on practices and procedures as developed by the laboratory and written in the ECP.



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#### 5. Containment

No work is to be conducted on the open bench with materials that have the potential for HIV, HBV, or HCV exposure.

A certified BSC must be used when working with materials that have the potential for HIV, HBV, or HCV exposure in the research laboratory. The BSC must be certified when installed, whenever moved, and at least annually.

Use of engineering controls (as noted in part D of this section) and PPE specific for splash and aerosol protection (protective clothing and respiratory protective equipment) are required when working with materials that have the potential for HIV, HBV, or HCV exposure.

## 6. Protective Clothing and Practices

Eye protection and laboratory coats, gowns, smocks, uniforms, or other appropriate protective clothing must be used in the work area and animal rooms. Protective clothing must not be worn outside the work area and, if reusable, must be autoclaved before being laundered.

Avoid skin contact with materials that have the potential for HIV, HBV, or HCV exposure. Gloves must be worn when handling infected animals and when handling these materials. Double gloves are recommended when exposure risk is high, e.g., when working directly with potentially infectious materials. See your lab-specific BSL2 w/3 practices BSM for more information.

#### 7. Use of Sharps

Hypodermic needles and syringes should be used only for parenteral injection of laboratory animals and aspiration of fluids from diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., the needle is integral to the syringe) should be used for the injection or aspiration of potentially infectious materials. See Appendix A.E.3., for essential work practices using sharps.

#### 8. Spills

Contain all spills immediately, and decontaminate as indicated for specific with biohazardous agents.

A spill or accident that results in an exposure incident must be immediately reported to the Pl/supervisor or other responsible person. Refer to <a href="EH&S Biohazardous Spills">EH&S Biohazardous Spills</a>.

#### 9. Decontamination of Waste

Before disposal, all waste from work areas and animal rooms must either be chemically decontaminated by a method that is known to effectively destroy BBP or autoclaved. The method of decontamination needs to be documented in your lab-specific BSL-2 with BSL 3 practices BSM.

Contaminated materials that are to be decontaminated at a site away from the work area need to be placed in a durable, leak-proof, labeled or color-coded container that is closed before being removed from the work area. The outside of the container must be decontaminated prior to removal from the lab (i.e., spray or wipe off the container).



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## 10. Additional Initial Training for Laboratory Staff and Workers in HIV, HBV, and HCV Laboratories

Laboratory staff and workers in HIV, HBV, or HCV research laboratories must receive the BBP training as outlined in your lab-specific BSL2 w/3 practices BSM. The PI/supervisor must ensure that laboratory staff and workers have experience in the handling of human pathogens or tissue cultures before working with HIV, HBV, or HCV, and must provide a training program to laboratory staff and workers who have no prior experience handling human pathogens. In this case, initial work activities can not include the handling of infectious agents.

A progression of work activities shall be assigned as techniques are learned and proficiency is developed. The PI/supervisor must ensure that laboratory staff participates in work activities involving biohazardous agents only after proficiency has been demonstrated. Practices and operations specific to the facility must be reviewed before allowing work with HIV, HBV, or HCV.

#### P. HIV, HBV, AND HCV PRODUCTION FACILITY

A HIV, HBV, and HCV production facility is a facility engaged in industrial-scale, large-volume production of high titer concentration of HIV, HBV, and HCV. There currently are no HIV, HBV, or HCV Production facilities at the University of Washington.



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## APPENDIX B – POSTING BIOHAZARD SIGNS AND LABLES

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#### A. PURPOSE

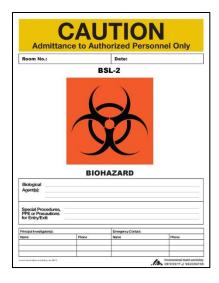
Biohazard warning signs are used to restrict access in areas when biohazardous procedures are in progress and to alert support personnel as well as emergency personnel who may enter the area to take precautionary measures.

#### **B. RESPONSIBILITY**

It is primarily the responsibility of the PI to identify and restrict access to the laboratory and to notify emergency and support personnel of any hazards in the laboratory.

#### C. BIOHAZARD WARNING SIGN USE

1. A standardized <u>Biohazard Warning Sign</u> must be used to restrict laboratory access.



- 2. This sign must be permanently affixed to all entry doors of the following laboratories/rooms:
  - BSL-2 with BSL-3 practices
  - BSL-3
  - ABSL-2
  - ABSL-2 with ABSL-3 practices
  - ABSL-3



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- 3. For BSL-2 laboratories, the Biohazard Warning Sign must be affixed to entry doors in a way such that it can be easily removed (e.g., place sign in plastic cover). After work is complete, agents are secured (e.g., inside closed incubator or refrigerator), and surfaces are decontaminated, the biohazard warning sign may be removed or turned over. If the biohazard warning sign is affixed to a BSL-2 laboratory door, support staff, such as Facilities Services or Custodial Services, will not enter.
- 4. Use the "Special Procedures, PPE or Precautions for Entry/Exit" section to list specific entry/exit requirements, PPE required for work and any occupational health requirements.

#### D. BIOHAZARD WARNING LABELS USE

Any storage or transportation container, as well as any waste container that contains untreated biohazardous waste, must be identified with a biohazard warning label. See the <u>Biological Research Safety page</u> for additional information about use of these labels and Appendix C for transportation information.

Examples of biohazard warning labels and order information are available from EH&S ROS at <a href="mailto:ehsbio@uw.edu">ehsbio@uw.edu</a> or 206 221-7770.



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# APPENDIX C – TRANSPORTING AND SHIPPING BIOHAZARDS

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## A. TRANSPORTING BIOHAZARDOUS AGENTS AND LABORATORY SPECIMENS

This section outlines the proper procedures for transporting biohazardous agents and laboratory specimens within buildings and between buildings. For procedures on transporting biohazardous waste, including recDNA waste, refer to Section 4.G.4 of this manual. Biohazardous agents must be packaged so that PPE is not needed during transport. PPE should not be worn in public corridors.

Transporting biohazards information is for moving biohazards to other research-related locations. Biohazards at the University are not permitted to be taken off campus to a private residence or for other purposes not related to or approved for institutional use.

## 1. Within Building

When packing biohazardous agents for transportation within the same building but through public areas, the following guidelines apply. UW Medical Center and Harborview Medical Center have specific requirements for transporting materials in their facilities. These requirements are found in each hospital's infection control manual.

- a. Biohazardous agents including specimens of blood or other potentially infectious materials must be placed in a primary container that prevents leakage during transportation. A test tube, for example, is a primary container.
- b. The primary container must be closed prior to being transported. The test tube, for example, must have a tight fitting cap or the cap must be taped in place or otherwise secured.
- c. Label the container with name of the PI and the room number.
- d. The primary container must be placed in a leak-proof secondary container. The test tube, in this example, is placed in a sealable plastic bag.

## 2. Between Buildings

When biohazardous agents are transported between buildings, the following guidelines apply.

- a. If using a motor vehicle for transport between buildings, it must be a UW owned and operated vehicle (e.g., Fleet Services, UCAR).
- b. Biohazardous agents, including specimens of blood or other potentially infectious materials, must be placed in a primary container that prevents leakage during transportation. A test tube, for example, is a primary container.



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- c. The primary container must be closed prior to being transported. The test tube, for example, must have a tight fitting cap or the cap must be taped in place or otherwise secured.
- d. Label the container with name of the PI and the room number.
- e. The primary container is placed within a leak-proof secondary container. The test tube, in this example, is placed in a sealable plastic bag. It is good practice to place absorbent material between the bag and tube to cushion the tube and absorb leakage from improperly sealed tubes. It is mandatory that absorbent material be used for items transported in a motor vehicle (UW owned and operated vehicle such as Fleet Services or UCAR for transport between buildings).
- f. The packages are then placed in an outer transport container labeled with the biohazard label. This container can be a cardboard box with a styrofoam liner, a cooler, or other sturdy transport container.
- g. If the material is not transported by the original packager (i.e., by courier or UW owned and operated vehicle) the outer transport container must show the following information in addition to the biohazard label:
  - Identification of the material being transported (e.g., human blood, animal blood, cultures, etc.)
  - The name, department, building, box number, and phone number of the receiving party
  - The name and phone number of the sender
  - The date sent

#### **B. SHIPPING BIOHAZARDOUS MATERIALS**

For <u>shipping biohazardous materials</u>, including infectious substances, contact EH&S Environmental Programs at 206-616-5835.

Anyone involved in packaging, shipping or preparing paperwork for the shipment of biohazardous materials, including infectious substances, must have task specific training:

- 1) Prior to beginning this assignment, and
- 2) Be re-trained every two years.



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## APPENDIX D – CURRENT RECORDS TO BE MAINTAINED

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The Biosafety Manual is augmented with laboratory-specific information that must be accessible to all employees in the laboratory at all times. Laboratory-specific information consisting of information such as standard operating procedures, laboratory floor plans, biohazard spill kit locations, exposure control plan, training records, and emergency procedures filed in this section and should be reviewed and updated by the PI or lab manager at least annually or whenever there are changes.

#### A. BIOSAFETY AND BLOODBORNE PATHOGENS TRAINING RECORDS

Laboratories must maintain current records of initial and refresher biosafety and BBP trainings.

EH&S maintains records of employee attendance at their classes. Copies of these records are available to departments upon request (call 206-543-7201 or email <a href="mailto:ehstrain@uw.edu">ehstrain@uw.edu</a>). You can also access your biosafety and BBP <a href="mailto:training records online">training records online</a>.

# B. CDC, U.S. DEPARTMENT OF AGRICULTURE, ANIMAL AND PLANT HEALTH INSEPCTION SERVICE PERMITS

PI must keep current copies of any required CDC, U.S. Department of Agriculture (USDA), or/and Animal and Plant Health Inspection Service (APHIS) permits.

#### C. AUTOCLAVE RECORDS

It is the responsibility of the principal investigator or laboratory/facility manager, and/or department to ensure compliance with all autoclave safety guidelines and the UW Biohazardous Waste Management Plan. Autoclave managers must maintain and post autoclave log sheets or a logbook near the autoclave, prepare a standard operating procedure (SOP) for each autoclave used to treat biohazardous waste, and maintain a training log for all users. These records must be kept for 6 years. A template SOP is available.



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## D. SHIPPING REGULATED MEDICAL WASTE (RMW) RECORDS

Laboratories must maintain records for the shipment of RMW for 6 years. These records must include the shipping papers provided by the waste contractor, site-specific standard operating procedures (SOPs), a training log of lab personnel, and shipping labels. A <u>template SOP</u> is available.

#### **E. SHIPPING PAPERS**

If items containing biohazards are mailed or moved on or off campus and require shipping papers, these papers should be kept for three years.

#### F. EXPOSURE INCIDENTS

Employee incident/accident report records are maintained at EH&S (206-543-7388). Industrial insurance records are maintained in the UW Office of Risk Management (206-543-0183). The PI should also keep copies of all incident/accident reports filed pertaining to the laboratory or involving laboratory staff.



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## APPENDIX E - WEB LINKS

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## A. REGULATIONS, GUIDELINES, STANDARDS, AND WEBLINKS

Animal Use Medical Screening (AUMS) Program

https://www.ehs.washington.edu/research-lab/animal-use-medical-screening-aums

#### Autoclaves

https://www.ehs.washington.edu/biological/biohazardous-waste

Biohazard Warning Sign

https://www.ehs.washington.edu/resource/biohazard-warning-sign-476

Biohazard Spill Kit

https://www.ehs.washington.edu/resource/how-make-biohazardous-spill-kit-96

**Biohazardous Spills** 

https://www.ehs.washington.edu/resource/biohazardous-spills-95

**Biohazardous Waste** 

https://www.ehs.washington.edu/biological/biohazardous-waste

Biohazardous Waste Management Plan

https://www.ehs.washington.edu/resource/biohazardous-waste-management-plan-91

**Biological Safety Cabinets** 

https://www.ehs.washington.edu/biological/biological-safety-cabinets

Biological Use Authorization (BUA Applications)

https://www.ehs.washington.edu/biological/biological-research-approval

Biosafety in Microbiological and Biomedical Laboratories

https://www.cdc.gov/labs/BMBL.html

Biosafety Stewardship

https://www.ehs.washington.edu/resource/biosafety-stewardship-120

Bloodborne Pathogens (BBP) Program

https://www.ehs.washington.edu/biological/bloodborne-pathogens-bbp-program



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**Biosafety Training** 

https://www.ehs.washington.edu/training/biosafety-training-online

CDC Information on Hepatitis B Vaccine

https://www.cdc.gov/vaccines/hcp/vis/vis-statements/hep-b.pdf

CDC Select Agent List

http://www.selectagents.gov/SelectAgentsandToxinsList.html

**CDC Select Agent Program** 

https://www.selectagents.gov/

Department of Comparative Medicine

http://depts.washington.edu/compmed/index.html

Dual Use Research of Concern

https://www.phe.gov/s3/dualuse/Pages/InstitutionalOversight.aspx

EH&S Exposure Response Poster

https://www.ehs.washington.edu/resource/exposure-response-poster-94

EH&S Guidance about Workplace Hazards Impacting Reproduction and Development

https://www.ehs.washington.edu/resource/guidance-workplace-hazards-impacting-reproduction-and-development-616

EH&S Spill Response Poster

https://www.ehs.washington.edu/resource/spill-response-poster-884

Embryonic Stem Cell Research Oversight (ESCRO)

http://www.washington.edu/research/escro/

**Employee Health Centers** 

https://www.ehs.washington.edu/workplace/employee-health-center

EPA Antimicrobial Chemical/Registration Number Indexes

https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants

IBC's Roles and Responsibilities

https://osp.od.nih.gov/biotechnology/institutional-biosafety-committees/

Institutional Animal Care and Use Committee

http://oaw.washington.edu/

International Society of the Advancement of Cytometry (ISAC)

http://isac-net.org/



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King County Board of Health

http://www.kingcounty.gov/healthservices/health/boh/code.aspx

Laboratory Safety Design Guide

https://www.ehs.washington.edu/resource/laboratory-safety-design-guide-515

My Training – EH&S Online Training Records Look-up

https://www.ehs.washington.edu/training/training-records

NIH Guidelines for Research Involving Recombinant DNA Molecules

https://osp.od.nih.gov/biotechnology/nih-guidelines/

Online Reporting System (OARS)

http://oars.ehs.washington.edu

Packaging Sharps and Lab Glass Waste poster

http://www.ehs.washington.edu/resource/packaging-sharps-and-lab-glass-waste-poster-92

Public Corridor Storage Policy

http://www.ehs.washington.edu/resource/corridor-policy-focus-sheet-209

Recombinant or Synthetic DNA in Human Research Participants

https://www.ehs.washington.edu/biological/clinical-trials

Seattle Municipal Code Infectious Waste Management

https://www.municode.com/library/wa/seattle/codes/municipal\_code?nodeId=TIT21UT\_SUBTITLE\_III\_SOWA\_CH21.43INWAMA\_21.43.050INWATR

**Sharps and Laboratory Glass** 

https://www.ehs.washington.edu/biological/sharps-and-laboratory-glass

Sharps Safety

https://www.ehs.washington.edu/research-lab/sharps-safety

**Shipping Hazardous Materials** 

https://www.ehs.washington.edu/chemical/shipping-hazardous-materials

Sharps Waste poster

https://www.ehs.washington.edu/system/files/resources/packaging-sharps-poster.pdf

Shipping Hazardous Materials Training

https://www.ehs.washington.edu/chemical/shipping-hazardous-materials

Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to

HIV and Recommendations for Postexposure Prophylaxis

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



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**UW Administrative Policy Statements** 

http://www.washington.edu/admin/rules/policies/APS/APSTOC.html

**UW Biosafety Manual** 

https://www.ehs.washington.edu/resource/biosafety-manual-4

UW Environmental Health & Safety Training

https://www.ehs.washington.edu/training

UW Health & Safety Programs: Policies and Responsibilities

http://www.washington.edu/admin/rules/policies/PO/EO55.html

UW Human Subjects Division (IRB)

http://www.washington.edu/research/hsd/

**UW Laboratory Safety Manual** 

https://www.ehs.washington.edu/resource/laboratory-safety-manual-510

**UW Radiation Safety Manual** 

https://www.ehs.washington.edu/resource/radiation-safety-manual-521

WAC 296-104-100, Autoclave Structural Inspection

http://app.leg.wa.gov/WAC/default.aspx?cite=296-104-100

WAC 296-823, Bloodborne Pathogen Standard

http://app.leg.wa.gov/wac/default.aspx?Cite=296-823

Washington Industrial Safety and Health Act, Homepage

https://app.leg.wa.gov/rcw/default.aspx?cite=49.17

Work Safely with Sharps Focus Sheet

https://www.ehs.washington.edu/system/files/resources/sharps\_safety.pdf

#### **B. WHERE TO FIND FORMS AND CHARTS**

Autoclave Biological Indicator Quality Control Checklist

https://www.ehs.washington.edu/system/files/resources/autoclave-gcbi.pdf

EH&S Biological Use Authorization Application

https://www.ehs.washington.edu/biological/biological-research-approval

EH&S Request for Change to Biological Use Authorization

https://www.ehs.washington.edu/biological/biological-research-approval

**Exposure Control Plan Template** 

https://www.ehs.washington.edu/biological/bloodborne-pathogens-bbp-program



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Hepatitis B Vaccination

https://www.ehs.washington.edu/biological/bloodborne-pathogens-bbp-program

Location-Specific Biological Waste Flowcharts

https://www.ehs.washington.edu/biological/biohazardous-waste

Notice of Laboratory Equipment Decontamination

https://www.ehs.washington.edu/resource/uw-form-1803-notice-laboratory-equipment-decontamination-154

