BIOSAFETY MANUAL

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I. INTRODUCTION

1.1 Purpose

This manual provides biosafety guidelines for those working at Oregon Health & Science University (OHSU), including any work that involves the handling of infectious microorganisms, human or animal tissues or body fluids, or research animals. This manual is meant to be a reference and provide guidance for addressing biosafety issues. This document is not meant to provide all biosafety requirements for highly specialized tasks, projects or locations at OHSU. The use of engineering controls, personal protective equipment (PPE) and modification of procedures are a few examples of ways to reduce the potential for exposure to biological agents. Supervisors are responsible for ensuring the health and safety of their employees. Individuals may perform procedures that require more stringent precautions than the general biosafety principles covered in this manual. Therefore, supervisors should evaluate each procedure and develop task-, project-, location- and/or device-dependent health and safety procedures to meet those requirements. Questions concerning biosafety practices or the development of specific protocols should be directed to the Biosafety Officer (BSO) in the Department of Environmental Health & Radiation Safety (EHRS).

1.2 Biosafety Issues

The biosafety issues of principle concern at OHSU are human bloodborne pathogens, zoonoses, experimental infectious agents and recombinant DNA (rDNA). Human bloodborne pathogens are discussed individually in the Bloodborne Pathogen sections. Select zoonotic agents of particular concern are discussed individually in the Animal Pathogens section. Projects involving experimental infections agents or rDNA are referred to the Institutional Biosafety Committee (IBC) or the campus BSO.

The Oregon Occupational Safety and Health Division (OR-OSHA) regulations specify the minimum requirements for exposures to human tissues/body fluids in OAR 437-002-0360 and 29 CFR 1910.1031, the Bloodborne Pathogen Standard[1]. One of the requirements is the development of a written Bloodborne Pathogen Exposure Control Plan. The guidelines presented in this manual are in compliance with OHSU policy as set forth by EHRS, and also address biosafety issues related to animal facilities and handling of animal tissues or body fluids. Thus, certain sections of the manual are written as specified in the Bloodborne Pathogen Exposure Control Plan and are specific for human tissue/body fluid exposures.

1.3 Abbreviations

ABSL	Animal Biosafety Level
APHIS	Animal and Plant Health Inspection Service
BMBL	Biosafety in Microbiological and Biomedical Laboratories
BSC	Biological Safety Cabinet
BSE	Bovine Spongiform Encephalopathy
BSL	Biosafety Level

BSO	Biosafety Officer
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CJD	Creutzfeldt-Jakob disease
DOT	Department of Transportation
DPS	Department of Public Safety
EHRS	Environmental Health & Radiation Safety
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HEPA	High Efficiency Particulate Air Filter
HIV	Human Immunodeficiency Virus
IACUC	Institutional Animal Care and Use Committee
IATA	International Air Transport Association
IBC	Institutional Biosafety Committee
NaOCl	Sodium Hypochlorite
NaOH	Sodium Hydroxide
NHP	Non-human Primate
NSF	National Sanitation Foundation
OAR	Oregon Administrative Rules
OHSU	Oregon Health & Science University
OPIM	Other Potentially Infectious Materials
OR-OSHA	Oregon Occupational Safety and Health Division
PI	Principal Investigator
PPE	Personal Protective Equipment
PrP	Prion Protein
rDNA	Recombinant DNA
RO	Responsible Official
SATs	Select Agents and Toxins
SIV	Simian Immunodeficiency Virus
SOP	Standard Operating Procedure
SPF	Specific Pathogen Free
TB	Tuberculosis
USDA	United States Department of Agriculture

II. PRINCIPLES OF BIOSAFETY/BIOSAFETY LEVELS

2.1 General Elements of Containment

Biosafety in Microbiological and Biomedical Laboratories (BMBL)[2], published by the United States Department of Health and Human Services, is the definitive reference on biosafety and should be read and followed by all OHSU personnel working with potentially infectious agents. This publication can be accessed on the Centers for Disease Control and Prevention (CDC) website.
http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm

Central to any discussion involving biosafety is the concept of containment of infectious agents to prevent contamination of the worker, nearby workers, or the environment. Containment is also utilized to prevent contamination of research samples or animals. There are three general elements of containment: 1) laboratory practices and techniques, 2) safety equipment, and 3) facility design. Each of these will be discussed briefly. For more detail, see the section on Principles of Biosafety in BMBL.

2.2 Laboratory Practices and Techniques

Strict adherence to standard microbiological practices and techniques is essential for successful containment. Studies have indicated that over 80% of laboratory infections cannot be traced back to an overt accident[3,4]. Most exposures and subsequent infections probably occur while performing routine procedures and techniques.

Every manipulation of a biological sample has the potential for releasing a portion of the sample in microdroplet form to the air and work surfaces. One simplistic but fundamentally valid way to view the potential for release of biological agents from a given sample is to consider the amount of energy that is used to manipulate the sample. High-energy techniques such as homogenization have the potential to release aerosols of the sample if not properly contained. However, even low energy procedures such as removing screw caps and pouring or stirring of liquid medium can release aerosols of the sample. Other examples of procedures that can generate aerosolized biohazards are washing down animal rooms, laboratory dishwashing, transferring tissue culture media, centrifugation and separating blood serum.

Aerosol formation has the potential to contaminate work surfaces, exposed skin and garments, and air in the breathing zone. Thus, aerosols can result in topical, oral, and respiratory exposures for workers. The results of one study investigating the formation of aerosols during common laboratory procedures[5] are shown in Table 1. It should be noted that some of the selected procedures involve the use of animals. These findings emphasize the importance of adhering to standard microbiological techniques, which minimize the total amount of energy to which a given sample is subjected during manipulation.

Table 1

Aerosols Created by Common Laboratory Procedures

Technique	Average Colonies Recovered from Air During Operation
Pipetting 10 ml culture into 1,000 ml broth	2.4
Drop of culture falling 12 in. (30 cm) onto:	
Stainless steel	49.0
Painted wood	43.0
Hand towel wet with 5% phenol	4.0
Re-suspending centrifuged cells with pipette	4.5
Blowing out last drop from pipette	3.8
Shattering tube during centrifuging	1183.0
Inserting hot loop into broth culture	8.7
Streaking agar plates	0.2
Withdrawing syringe and needle from vaccine bottle	16.0
Injecting 10 guinea pigs	16.0
Making dilutions with syringe and needle	2.3

Using syringe/needle for intranasal inoculation of mice	27.0
Harvesting allontoic fluid from 5 eggs	5.6

Personal hygiene practices provide the simplest yet most important manes for preventing disease transmission. This is especially true for workers who directly handle animals or animal tissues/body fluids. Practices such as routine hand washing at each available opportunity can be very successful in preventing contamination of more susceptible regions of the body as well as inanimate surfaces.

Specifics on standard microbiological practices and techniques are discussed in more detail in the Standard Biosafety Practices section of this document and in BMBL. Development of, and adherence to, standard microbiological practices is fundamental to the practice of biosafety. Safety equipment and laboratory design cannot be counted on to compensate for a lack of these practices.

2.3 Safety Equipment

Safety equipment includes safety centrifuge cups, biological safety cabinet (BSCs) and enclosed containers. Safety equipment also includes PPE such as gloves, coats, coveralls, show covers, boots, respirators, face shields, safety glasses and goggles. Safety equipment is often referred to as a primary barrier, since it generally represents the initial barrier(s) of protections downstream from standard microbiological practice.

Combinations of various types of safety equipment can be used to create more than one primary barrier. However, circumstances may make it impractical to use equipment such as BSCs or completely enclosed containers, leaving PPE as the only primary barrier between the worker and a sample containing an infectious agent. This again illustrates the importance of standard microbiological practices because of the potential for PPE or other safety equipment failure. The use of safety equipment is discussed further in BMBL.

2.4 Facility Design

The design of a facility used to conduct research involving specific biological agents is highly dependent on the epidemiology and the risk and route of transmission associated with those agents. Facility design is viewed as a secondary barrier to protect workers, both inside and outside the facility. These secondary barriers may include separation of the laboratory work area from public access, availability of a decontamination area, hand washing facilities, specialized ventilation systems to assure directional airflow, air treatment systems to decontaminate or remove agents from exhaust air, controlled or restricted access zones, airlocks at laboratory entrances, and separate buildings or modules for isolation of the laboratory. More information on design criteria for specific agents and biosafety levels is found in BMBL.

As risk of transmission increases, the number of requirements for facility design also increases. Evaluation of risk associated with a given human pathogen is a highly subjective task. The epidemiology and etiology associated with a specific human pathogen may be a steadily evolving course of events. Thus, facility design should not be viewed as a substitute for standard microbiological practices. To

minimize risk of transmission, the first aspect to consider is engineering controls, followed by administrative controls. The last route of protections should be the wearing of PPE.

2.5 Biosafety Levels

It is not the intent of the manual to establish the required biosafety level (BSL) for all tasks, projects and locations at OHSU. However, this manual does present the requirement for all Principal Investigators (PIs) or supervisors to determine the hazards associated with a given process or project and take the steps necessary to protect workers. This process may require the establishment of a minimum BSL.

Assignment of BSL to a given project is highly sensitive to the risk(s) and route(s) of transmission associated with a specific infectious agent. There are four levels of biosafety assigned to operations conducted in laboratories. These are generally referred to simply as BSLs 1-4. For those operations that involve the use of animals there are also four levels of biosafety distinguished as animal biosafety levels (ABSLs) 1-4.

BSL-1 is appropriate for agents not known to consistently cause disease in health adult humans. These agents are of minimal potential hazard to laboratory personnel and the environment. Examples are Bacillus subtilis, Naegleria gruberi, and infectious canine hepatitis.

BSL-2 is applicable for agents that have a moderate potential hazard to cause disease in healthy adult humans and pose a moderate risk to the environment. If a worker contracts a disease related to BSL-2 agents, treatment is generally available. Examples are: Hepatitis B Virus (HBV), salmonellae, and Toxoplasma spp.

BLS-3 is used for agents that may be indigenous or exotic and are an aerosol transmission hazard. Diseases in this category may have serious health effects and treatment may or may not be available. Examples are: Mycobacterium tuberculosis (TB), Coxiella burnetii, and St. Louis encephalitis virus.

BSL-4 is required for agents that are dangerous or exotic and pose a high risk of life threatening disease, are aerosol transmissible, or are related agents with unknown risk of transmission. Treatment for infections by these agents is generally not available. Examples are: Marburg virus and Ebola virus.

BSL assignment should be conducted on a case-by-case basis. Reference to BMBL may simplify the process of selecting the BSL for a project by cross-referencing a large number of known human pathogens with the recommended BSL or ABLS requirements. However, the information for each agent in the BMBL represents the current knowledge base only for those agents and the listing of agents is not all-inclusive.

The BSL determination for an agent should have many criteria investigated and could result in being placed in a higher or lower BSL than what the literature recommends, depending on what manipulations are occurring. Some aspects to consider when determining the BSL rating include: the concentration of the agent, the type of manipulations proposed, and the training/experience of the individual performing the task. An example might be a BSL-2 agent that has been molecularly manipulated to increase the pathogenicity so that its status changes from a BSL-2 agent to a BSL-3 agent. Another example would be a BSL-2 agent that is being concentrated for use in the laboratory. The concentration of the agent may

be such that aerosol transmission is not a possibility. This would result in the raising of the status to BSL-3 criteria.

III. RISK ASSESSMENT

3.1 General Discussion

Each time an individual at OHSU works with any animal or biological sample that may be a reservoir for a human pathogen, that individual has carried out a risk assessment concerning the potential for disease transmission under a given set of circumstances. This is true regardless of that individual's experience and educational background. The real issue is not whether or not a risk assessment has occurred, but rather how thoroughly the assessment has been conducted. **Supervisors are responsible for the safety of any assigned employees and should be consulted for assistance regarding specific hazards of the task.**

Risk assessment for a given activity that includes work with infectious agents is a subjective process. Inherent in any risk evaluation of this nature is the extent of knowledge concerning the potential for transmission of a given agent while performing a specific activity. This clearly points to the need to do risk assessment on a case-by-case basis. Some aspects to consider when performing a risk assessment include the task being performed, the potential for aerosolization, concentration of the agent, the route of infection, and the consequences of infection.

3.2 Exposure Determination

Federal regulation 29 CFR 1910.1030(c)(2)(i) requires that all workplaces with potential occupational exposures to human tissues or body fluids perform an Exposure Determination[2]. OR-OSHA defines occupational exposures as reasonably anticipated skin, eye, mucous membrane or parenteral contact with human blood or other potentially infectious materials (OPIM) while performing occupational duties. OPIM includes:

Semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids.

Any unfixed tissue or organ, other than intact skin, from a living or dead human.

HIV-containing cell or tissue cultures, organ culture, and HIV, HBV, or Hepatitis C Virus (HCV) containing culture medium or other solutions, and blood, organs or other tissues from experimental animals infected with HIV, HBV, or HCV.

Below is a list of non-hospital job classifications in which some employees at OHSU have potential occupational exposure to bloodborne pathogens.

Assistant Professor	Janitor	Research Associate
Assistant Scientist	Lab Aid	Research Fellow
Associate Professor	Medical Technician	Scientific Instrument Technician
Associate Scientist	Postdoctoral Fellow	Scientist
Facilities Technician	Professor	Visiting Scientist
Graduate Student	Research Assistant	

The following is a list of tasks and procedures, or groups of closely related tasks and procedures, in which occupational exposure can occur. Employees in job classifications listed above perform many of these tasks and procedures.

Disinfecting	Instrument/surface decontamination	Pipetting
Processing human samples	Phlebotomy	Solid/liquid waste handling
Centrifugation of body fluids	Physical manipulation of body fluids	Thin sectioning of tissue
Dishwashing	Physical manipulation of tissues	Tissue culture

3.3 Institutional Biosafety Committee

The IBC is responsible for evaluating all research that is conducted with rDNA, infectious agents, or biological toxins, regardless of funding source, in order to oversee the health and safety of employees and the public, and to ensure compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules. While several types of studies may be eligible for exemption from review, no investigator may exempt him/her self from review. The IBC has sole authority to exempt studies from review. Consult the IBC website (http://www.ohsu.edu/research/rda/ibc/) for additional information about the IBC and its policies and procedures.

3.4 Principal Investigator Responsibilities

PIs are responsible for identification of potential biosafety issues that are inherent to a specific project. This information should be disseminated to all potentially exposed individuals and procedures should be adopted to protect those individuals. Although there will always be unknowns, the PI should be aware of typical procedures involving the use and corresponding hazards associated with animals, animal tissues/body fluids, human tissues/body fluids and infectious agents. All individuals involved with, or who assist in, projects involving animals, animal tissues/body fluids, human tissues/body fluids and infections agents should be made aware of specific biohazards that exist and methods of protecting against the hazard.

1. The IBC must be informed by the PI of all research involving rDNA, infectious agents or biological toxins prior to project initiation. The process for approval of research involving such agents is outlined on the IBC website, and includes:
2. The PI completes the Initial Recombinant DNA Research Classification, Recombinant DNA Research Questionnaire, and/or OHSU Infectious Agent/Toxin Questionnaire as appropriate for the project.

3. The completed forms are evaluated by the IBC Manager, and additional information is requested from the PI if necessary.
4. The proposal is reviewed by the IBC if required.
5. An approval or exemption letter is provided to the PI stating any restrictions or recommendations that must be met before the project may begin.

For more information regarding projects involving rDNA or infectious agents contact the IBC Manager or the campus BSO.

OHSU has the resources available to assist PIs with any required investigations into potential biohazards. In many cases, an investigation may be as simple as consulting BMBL. Assistance with detailed biosafety investigations may be requested from EHRS.

Specific PI responsibilities necessary to accomplish the broad goal of protecting staff working with potential biohazards are listed below:

1. Comply with all applicable OHSU Biosafety Manual guidelines.
2. No research requiring IBC approval may be started or modified prior to receiving approval and making arrangements with animal care management.
3. No research involving animals may begin prior to obtaining approval from the Institutional Animal Care and Use Committee (IACUC).
4. Make an initial determination of appropriate microbiological practices and biohazard containment equipment to be used for a given project.
5. Make copies of information available to staff that describe potential biohazards and precautions to be taken.
6. Instruct and train staff in the practices and techniques required to ensure safety. Training should be specific regarding potential infectious agents and established Standard Operating Procedures (SOPs).
7. Inform staff of the reasons and provision for any required precautionary medical practices, such as vaccinations.
8. Report all significant incidents/accidents to the BSO.
9. Ensure the integrity of physical containment devices, such as BSCs.
10. Comply with all infectious agent shipping and receiving requirements.
11. Supervise the safety performance of staff to ensure the use of required biosafety practices and techniques.
12. Evaluate any safety procedures or SOPs to assure their continued effectiveness and practicality.

IV. STANDARD BIOSAFETY PRACTICES

The biosafety practices discussed in this section address worker exposures to laboratory animals, animal tissues/body fluids, and human tissues/body fluids. Although there are many similarities between the biosafety practices demanded by work involving laboratory animals and work involving human and animal tissues/body fluids, there are also a substantial number of differences. Therefore, biosafety practices for work with laboratory animals and biosafety practices for work with human and animal tissues/body fluids are discussed separately in this section.

4.1 Animals

Infections from animals may, on some occasions, produce significant disease in humans. These infections are called zoonotic diseases. They are transferred from animals to humans by one, or a combination of, the following routs: contact, ingestion, inhalation, or injection. In many cases, the animal shows little, if any, sign of illness. One should always be aware of possible consequences when working with each type of animal and take precautions to minimize the risk of infection. The scope of possible zoonotic diseases is quite large. It is important to have information regarding the specific diseases associated with the type of animals you may work with or around. Personnel who have suppressed immune systems are at an increased risk of zoonotic disease infection.

When working around animals the following precautions should be followed:

1. Wash hands frequently, especially when leaving the animal area and before eating, drinking, or smoking.
2. Avoid the use of sharps whenever possible.
3. Keep hands away from the face.
4. Do not eat, drink, smoke, handle contact lenses, take medications, or apply cosmetics in animal areas.
5. Wear appropriate PPE.
6. Do not recap needles.
7. Be aware of your proximity to the animal to avoid accidental direct contact.

Special practices may be employed when infections agents are used experimentally, or as circumstances require. Training is necessary on any special practices or precautions before work can begin.

Access to animal housing, use, and support areas is limited to authorized, trained, and informed personnel. Only those individuals with work-related requirements, and who have had the appropriate training, may be in animal areas unescorted. Visitors or service technicians who have not received training must be escorted by an OHSU representative trained in biosafety procedures at all times while in animal areas.

Cross-infection occurs between laboratory animals and/or animal tissues/body fluids and personnel, usually via one of the following routes:

1. Primary exposures (bites, scratches, aerosols, topical exposure, accidental inoculation, etc.) from infected animals or their tissues/body fluids obtained directly from the wild or uncontrolled conditions (e.g., non-human primates, dogs, cats, farm animals).
2. Primary exposure to animals with laboratory-acquired latent infection (infections in a sub-clinical state, which manifest themselves during periods of stress).

Non-human Primates (NHPs) are generally considered to be the species with the greatest risk of perpetual infection or re-infection with zoonotic diseases. Humans are susceptible to a variety of infections carried, often in a sub-clinical state, by NHPs. Tissues or body fluids collected from NHPs may be hazardous, sometimes even after fixation, prolonged storage or subculture. Further hazards are

associated with the use of NHPs as host-models in experimental infections with human diseases. See Section 4.3 Specific pathogens by Animal Type for more information regarding specific agents of concern.

All personnel musty wear appropriate PPE to protect against animal related hazards. Common examples of PPE utilized in animal areas include: eye and face protection, hand and body protection, foot protection, and possibly respirators. The selection of PPE should be based upon risk to the worker. The employee's supervisor is responsible for ensuring proper PPE is being worn. EHRS can assist with questions regarding PPE selection.

Eye protection is required for all personnel and any visitors whose eyes may be exposed to chemical, biological or physical hazards. Any PPE designated for eye and face protection should meet the requirements listed in ANZI Z87.1. General eye and face protective designs include:

1. Safety glasses for protection against flying particulates.
2. Safety goggles for protection against fumes, splashes, mists, or sprays.
3. Face shields to protect against exposures to the face. Face shields should not be used as a substitute for eye protection, and it may be necessary to provide both means of protection.
4. Fiber masks to protect the nose and mouth from direct exposure.

Hand and body protection is required when working with animals or animal tissues/body fluids that can cause a significant exposure through skin contact. Appropriate gloves, lab coats, and other personal protection should be selected to meet the needs of the specific agents, tasks, and work environment. General requirements for hand and body protection include the following:

1. Hand protection. Gloves are required to protect the hands and arms from biological materials that may result in absorption through the skin or reaction on the surface of the skin. Glove materials must be chosen with the specific tasks and agents used in mind (type of material, thickness, permeation rate, and degradation rate). Gloves should be inspected for defects or tears before and after each use. Gloves should be removed when exiting the work area. Always wash hands after removing gloves. Latex or nitrile gloves are generally acceptable for most bloodborne pathogens associated with humans and animals.
2. Body protection. Personnel in any area where biological materials are routinely used or stored should wear a body covering. Body coverings should be removed when exiting the work area and removed immediately if contaminated with hazardous materials. Lab coats should never be laundered at home. Each area should have a procedure established for lab coat laundry service. Contact the area supervisor of EHRS if there are any questions regarding body coverings. Acceptable body coverings are dependent on the area and may include lab coats (routine bench work, non-specific pathogen free (SPF) rodent areas), disposable long sleeved aprons (SPF areas, ABSL-2 areas), disposable Tyvek coveralls (quarantine areas, ABLS-3 areas, NHP corrals), or long sleeved water resistant nylon overgarments (routine work within the animal areas). Clothing that exposes large areas of skin, leaving them unprotected (i.e., shorts, sandals, skirts, etc.), is not allowed in areas where biological hazards exist, even with PPE.
3. Foot Protection. Open toed shoes should not be worn when working in animal housing areas of areas where biohazardous materials are being handled. Shoe covers are available as additional protections against gross contamination of shoes and may be required in certain work areas.
4. Respirators. In certain situations where engineering controls cannot effectively control air contaminants within the work environment, personnel may be required to wear respiratory

protective equipment. However, this is not a desirable situation. The use of BSCs should normally be sufficient to prevent the need for respirators. Personnel designated to use respiratory equipment must first have appropriate medial approvals, fit testing, and training. Contact EHRS before wearing any respirator.

All unescorted personnel and visitors must receive training on health and safety issues before the individual begins work in the areas and animals with which they may have contact. This training should occur before the individual begins work in the area. Training should include information on the Occupational health Program, zoonotic diseases of concern, disease transmission prevention, personal Hygiene, PPE selection, and accident and exposure reporting procedures. The supervisor is responsible for ensuring that their workers have received adequate training.

All wounds should be washed *immediately* with soap and water for 15 minutes using a massaging motion. If the exposure involves mucous membranes, rinse the area with water for 15 minutes. The potential for various zoonotic disease infections depends upon a variety of circumstances, including time from exposure to thorough cleaning, route of transmission, immune status of the exposed individual, species of animal, and characteristics of the agent. A medical evaluation may be necessary for some types of exposures.

Immediately after washing the wound or exposure site, report the incident to the supervisor or person in charge of the area. Exposures to NHP fluids can be extremely serious. Exposures to macaque tissues or fluids should be reported to the veterinarian on call immediately after washing. More specific information on exposure procedures for animal hazards can be found in Section 4.3 Specific Pathogens by Animal Type.

4.2 Human or Animal Infectious Agents

These recommended practices apply to working with agents that could be infectious to humans or animals:

Observe universal precautions. This means that ALL potentially infectious biological materials are handled as if known to be infectious.

Personal hygiene is the primary defense against animal-to-human and human-to-human disease transmission. The following personal hygiene practices should be followed:

1. Wash hands immediately after removal of gloves or other PPE.
2. Wash hands when leaving an area where infectious biological agents are handled, regardless of whether you handled the agent yourself.
3. Immediately wash any skin site topically exposed to potentially infectious biological agents with soap and water for 15 minutes.
4. Wash hands before eating, drinking, smoking, inserting contact lenses, or chewing gum.
5. Wash hands before leaving the facility.

Clothing. And PPE that is appropriate both for the task to be performed and the location of the task, is to be selected and worn at all times. PPE is considered ”appropriate” only if it does not permit infectious

biological fluids or tissues to reach the employee's street clothes, scrubs, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time the protective equipment will be used. The following is the minimum PPE to be worn when working with potentially infectious biological agents:

1. Long sleeve lab coat, long sleeved disposable or water resistant nylon overgarment or coverall.
2. Fiber face mask.
3. Latex, PVC, or nitrile gloves.
4. Leg and foot covering (no shorts, skirts, dresses, or open toed shoes) when in areas where infectious agents are present.
5. Eye protection, prescription or non-prescription. Wrap-around safety glasses will generally be adequate, but safety goggles or face shields may be necessary.
6. Bouffant or hood, and shoe covers or boots, should be work in instances when gross contamination or aerosols can be reasonable be anticipated (e.g., necropsy, cage washing, etc.)

Area supervisors or EHRS should be contacted if there are questions concerning selection of PPE.

Contaminated laundry should be handled as little as possible and with a minimum of agitation. Contaminated laundry should be bagged or containerized at the location where it is used; it should not be sorted or rinsed at the location of use. Contaminated laundry is to be placed in containers labeled with the universal biohazard symbol. Whenever contaminated laundry is wet and presents a reasonable likelihood of soak-through or leakage from the container, the laundry should be placed and transported in bags that prevent external contamination. Contaminated laundry should never be taken home.

Do not eat, drink, insert contact lenses, apply cosmetics (including lip balm) or smoke in laboratories where infectious biological fluids are handled. Food and drink should not be kept near where infectious agents are present. Freezers and refrigerators that contain infectious agents should be marked with a universal biohazard and "No Human Food" sign. Mouth pipetting/suctioning of potentially infectious fluids or OPIM is prohibited. Disposable (single use) gloves should not be washed our reused.

Contaminated needles and other contaminated sharps should not be bent, recapped or removed unless it can be demonstrated that no alternative is feasible or that such action is required by a specific procedure. If recapping or needle removal is required, techniques and/or devices should be used that minimize potential risk. The use of self-sheathing or retractable needles is preferred when needles must be used.

Potentially contaminated PPE is not to be worn outside the work area. Potentially infectious items transported outside work areas are to be decontaminated prior to transport or transported in decontaminated secondary containment. This practice negates the need to wear gloves during transportation. If gloves will be needed at a location where they are not supplied, they must be taken there, not worn to the location. The only exceptions to this rule are as follows:

1. Transport of items within a group of associated of jointly used laboratory rooms within the same building.
2. Transport of live animals outside of containment.
3. Transporting cages for the purpose of decontamination.

Frozen tissue shall be handled in the same manner as non-frozen tissue. Freezing should not be considered a means of inactivation of biological agents.

All surfaces should be cleaned and decontaminated with an appropriate disinfectant after contact with potentially infectious material. For more information, see Chapter VIII, Decontamination. Work surfaces should be decontaminated with an appropriate disinfectant after completion of procedures, immediately when surfaces are overtly contaminated, and at the end of the work shift if the surface may have become contaminated since the last cleaning. Protective coverings such as plastic wrap, aluminum foil or imperiously backed absorbent paper used to cover equipment and environmental surfaces should be removed and replaced when they become overtly contaminated.

All bins, pails, cans and similar receptacles intended for reuse and where contamination with blood or OPIM is likely, shall be inspected and decontaminated on a regularly scheduled basis and decontaminated immediately upon visible contamination. Broken glassware that may be contaminated should not be picked up directly with the hands, it should be cleaned up using mechanical means (brush and dustpan, tongs, forceps, etc.).

Reusable sharps that are contaminated should not be stored or processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed. Dewars used to hold coolant for freezing tissue are to be decontaminated after the coolant has been poured out or has evaporated. Frozen tissue still presents a biohazard. Cryostats should be decontaminated on a regular basis, especially during defrosting. Since cryostats have an inherent cut hazard from the blades used to cut tissue, exposures due to cuts in cryostats should be considered to be serious.

Warning labels indicating the presence of a biohazard should be affixed to containers of infectious waste, refrigerators and freezers containing infectious agents, and other containers used to store, transport or ship biological materials. All labels used should include the universal biohazard symbol. Red biohazard bags or red biohazard containers may be substituted for labels. Universal Biohazard signs should be posted at the entrance to any work area where experimentally infected materials or animals are present. A sign indicating the agent being used and names and phone numbers of responsible individuals to be contacted in an emergency should accompany the biohazard sign.

A contaminated sharp is any contaminated object that can penetrate the skin, including but not limited to: needles, scalpels, broken contaminated glass and broken capillary tubes. The definition also includes new or used syringes with or without needles. The use of needles and syringes should be restricted to those procedures for which there is no alternative. Use needles, syringes, glass Pasteur pipettes and other sharps carefully to avoid injuries. Use needle safe devices whenever possible. Dispose of sharps in red, leak-proof and puncture-resistant sharps containers.

Biological Safety Cabinets (BSCs) are often referred to as tissue culture hoods. BSCs are the primary engineering control that researchers working with tissues, cultures and fluids from animals or humans use to protect both themselves and their samples from contamination. BSCs are available in three general types, Class I, Class II and Class III, although Class I BSCs are no longer manufactured on a regular basis. BSCs are independently tested by the National Sanitation Foundation (NSF), using test protocol NSF-49[6]. Performance testing includes:

1. High Efficiency Particulate Air (HEPA) filter leak testing,
2. Personnel, product and cross-contamination protection testing,

3. Work access opening airflow (face velocity) testing, and
4. Airflow smoke patterns testing.

The requirements for BSC use at OHSU are:

1. BSCs should be used for all techniques involving the use of biological material where there is a significant potential for the generation of infectious aerosols,
2. A fume hood should not be used in the place of a BSC or vice versa,
3. All BSCs at OHSU should meet the NSF standard 49 and be certified at least annually by a qualified technician. EHRS has a list of qualified technicians for referral.

Personal vehicles can be used to transport biological materials only if the samples are placed in a secondary container and this is placed into a third level of containment that should be used exclusively for sample transport and can be decontaminated by autoclaving or by chemical treatment. All containers must be labeled with a universal biohazard sign, positioned in such a way that the container remains upright and placed as far away as possible from the driver (e.g., trunk of car). Rodents are not to be transported in personal vehicles if they are known to be infected with human pathogens. Personal vehicles can be used to transport live or dead rodents known to be free of human-related pathogens if properly labeled secondary containment that can be decontaminated by autoclaving or chemical treatment is used. Personal vehicles cannot be used to transport NHPs.

Tissue fixation normally involves the use of an aldehyde compound or mixture of aldehyde compounds to “fix” the sample. On a chemical basis, the aldehyde compound(s) may react with any and all hydroxyl and amino groups in the tissue. This includes hydroxyl and amino groups that are a part of the chemical composition of any infectious agents present. The aldehyde compound reacts with these groups to form imine, hemiacetal and acetal groups. The ultimate chemical result is dependent upon:

1. The reactive functional group available (hydroxyl or amino)
2. The molecular logistics of the reactive functional group relative to other reactive functional groups, and
3. The mono- or di-functionality of the aldehyde used.

The term “fix” is technically accurate in many cases, since depending on the above three variables, the aldehyde chemically cross links reactive functional groups in the tissue on a random basis, as well as reactive functional groups associated with any infectious agents present. Generally, the formation of imine, hemiacetal or acetal groups, and especially cross links involving these groups will bring any functioning chemical machinery (i.e., viable infectious agents) to a halt. <u>However, when insufficient aldehyde is used, insufficient time is allowed for thorough fixation or tissue permeability is low, incomplete fixation may result.</u> Other variables such as tissue thickness and logistical availability of reactive functional groups within the tissue can also significantly influence completeness of fixation. Both bacterial and viral agents have been shown to resist fixation in aldehydes, either due to inherent characteristics or those variables discussed above. Tissue fixation presents a number of uncontrolled variables. For this reason, the following recommendations should be followed at OHSU:

1. Standard tissue fixation procedures should be used when fixing any biological samples. Maximum feasible fixation time should be allowed prior to handling samples.
2. All fixed biological samples should be handled in the context of Universal Precautions.
3. Appropriate PPE should be worn to protect the worker against exposure to the fixative(s).

A limited number of tasks, projects and locations at OHSU will require development of a written specialized biosafety protocol. These specialized protocols are required when the infectious agents that are or may be present demand a specific biosafety practice outside the general biosafety practices included in this manual. An example of this is a procedure for entering a BSL-3 laboratory. Another example is minimum PPE requirements for necropsy. These protocols must be written and maintained by individuals with detailed knowledge concerning risk assessment for the specific task, project or location. Assistance with the construction of these documents can be obtained from EHRS.

Access to laboratories where pathogenic agents are processed should be limited to authorized, trained and informed personnel. Only those individuals with work-related requirements should be in these areas. An OHSU representative with training in proper biosafety procedures should escort visitors at all times.

Appropriate post-exposure procedures are of extreme importance in reducing the risk of disease transmission. Exposures involving infectious agents require immediate attention. For exposures to skin, regardless of whether they involve intact or broken skin, wash with soap and water continuously for a minimum of 15 minutes. Apply a clean, sterile bandage if appropriate. For exposures involving the eyes, or other mucous membranes, flush with clean water for 15 minutes.

All exposure incidents must be reported immediately. The purpose of reporting immediately is to alert OHSU management to conditions that could lead to further injuries or illnesses. Laboratory incidents that involve eye, mouth, other mucous membranes, non-intact skin or skin breakage, or parenteral contact with infectious agents are to be reported to the supervisor after initially washing the area. For incidents involving live animals, report all bites, scratches (direct from the live animal), contaminated needle/sharps sticks and mucous membrane exposures wash the area as soon as possible then report the incident to the supervisor and the attending veterinarian. Human tissue related incidents should be reported to the supervisor and the Employee Health Department. All incidents should also be reported on OHSU Incident Report forms. The Incident Report form assists the safety committee in reviewing the incident for suggestions of risk reduction strategies. Incident forms can be found on the Risk Management website.

The OR-OSHA Bloodborne Pathogen Standard requires employers to establish and maintain an accurate record for each employee that sustains an occupational exposure to human tissues and/or body fluids. The Employee Health and Risk Management Departments are responsible for keeping records on human tissue/body fluid exposures. This record consists of the following:

1. The name and social security number of the employee.
2. A copy of the employee's HBV vaccination status, including the dates of all the HBV vaccinations and any medical records relative to the employee's election to receive vaccination.
3. A copy of all results of examinations, medical testing, and follow-up procedures as noted in the OHSU Exposure Control Plan.
4. The employer's copy of the health care professional's written opinion post-exposure.
5. A copy of the information provided to the health care professional post-exposure.

OHSU must ensure that employee medical records are kept confidential and not disclosed or reported, without the employee's express written consent, to any person within or outside the workplace except as required by law. OHSU will maintain these records for the duration of employment plus 30 years.

4.3 Specific Pathogens by Animal Type

Rodents.
Rodents housed at OHSU are generally free of specific pathogens including zoonotic organisms. However, the following is a list of diseases/agents that are often associated with rodents:

Toxoplasmosis. Although this disease can be very serious in pregnant women and typically does not present unique symptoms, laboratory animals are not usually carriers of this agent unless they are experimentally exposed. Appropriate PPE will greatly reduce the potential of disease transmission.

Tapeworm. Most often tapeworm infection does not present unusual symptoms. Symptoms may include abdominal discomfort and/or diarrhea. Diagnosis of infection is confirmed by examination of a stool specimen.

Salmonella. This bacterial disease is characterized by abdominal pain, fever, diarrhea and dehydration. Individuals with infection may be very ill for several days to weeks. Wearing appropriate PPE and using good hand-washing practices will reduce the potential of contracting this illness.

Ringworm and other dermatomycoses. These agents cause fungal infections of the skin that are rarely serious. The fungus may survive for extended periods of time on inanimate objects. Wearing appropriate PPE and using good hand-washing practices will reduce the potential of acquiring these infections.

Allergies. Symptoms of allergies include watery eyes, runny nose, difficulty breathing or rashes. The development of secondary allergies (allergies to more than one animal) is also problematic. Personnel are highly encouraged to wear appropriate PPE (eye protection, fiber mask, bouffant, disposable gloves, body covering and shoe covers) when handling rodents to reduce the potential of allergic reactions. Other measures that can be employed to reduce exposure to allergens from animals include administrative controls (animal stock density, wet shaving, etc.), environmental controls (filter topped cages, ventilation which includes HEPA filtered room air, increased air exchanges and low dust or dust free bedding), use of HEPA respirators and special housekeeping routines (wet mopping and water hosing). For additional information see Section 4.4 Laboratory Animal Allergens.

Suggested PPE for individuals handling rodents: eye protection, fiber facemask, gloves, body covering.

Cats.
The following is a list of diseases/agents that are often associated with cats:

Cat scratch disease. This disease is characterized by regional lymphadenitis that follows a skin papule at the site of the cat scratch. While the disease is self-limiting in most cases, a physician evaluation is recommended.

Toxoplasmosis. Cat feces are the most common source of the agent causing this disease. Although this disease can be very serious in pregnant women it typically does not present unique symptoms. Pregnant women without immunity to toxoplasmosis should not be exposed to *infected* animals.

Campylobacteriosis. This disease is the leading cause of diarrhea in humans and animals. Symptoms include acute gastrointestinal illness that is usually self-limiting but can become quite serious. Transmission is typically oral-fecal so wearing appropriate PPE and practicing good personal hygiene habits can reduce the potential of acquiring this illness.

Pasteurellosis. This disease is caused by a bacteria commonly carried in the respiratory tract and oropharynx of a large percentage of healthy cats that is spread by animal bites. Symptoms of infection include swelling and pain out of proportion to the visible wound and swollen lymph nodes with generalized infection. Onset is typically less than 24 hours after the bite occurs.

Ringworm and other dermatomycoses. See Rodents section (above).

Allergies. See Rodents section (above).

Suggested PPE for individuals handling cats: eye protection, fiber facemask, gloves, body covering.

Special considerations: If cats are not negative for toxoplasmosis, pregnant workers should be evaluated for immunity to toxoplasmosis before exposure to cat fecal material.

Dogs.
The following is a list of diseases/agents that are often associated with dogs:

Parasites. Parasites such as larval migrans, tapeworms and sarcoptic mange are a potential risk to those handling infected animals. Infections from these agents are sometimes without symptoms.

Leptospirosis. This group of bacterial agents has common symptoms of sudden fever, headache, chills, sever muscle aches and other meningitis type symptoms. The illness can last from days to weeks, and untreated cases can take months to recover. Disease transmission occurs through contact of mucous membranes or broken skin with infected urine.

Brucellosis. This bacterial infection produces flu like symptoms and profuse sweating. Mortality is rare, but it is not unusual for patients to have some disability after recovery. Brucellosis is transmitted by direct contact with contaminated tissues or fluids.

Pasteurellosis. This disease is caused by a bacteria commonly carried in the respiratory tract and oropharynx of healthy dogs that is spread by animal bites. Symptoms of infection include swelling and pain out of proportion to the visible wound and swollen lymph nodes with generalized infection. Onset is typically less than 24 hours after the bite occurs.

Campylobacteriosis. This disease is the leading cause of diarrhea in humans and animals. Symptoms include acute gastrointestinal illness that is usually self-limiting but can become quite serious. Transmission is typically oral-fecal so wearing appropriate PPE and practicing good personal hygiene habits can reduce the potential of acquiring this illness.

Suggested PPE for dog handlers: eye protection, fiber facemask, gloves, body covering and shoe covers.

Farm Animals.

The following is a list of diseases/agents that are often associated with farm animals (cows, horses, pigs, sheep, etc.):

Q fever. Coxiella burnetii is the causative agent of Q fever, which can be a serious disease in humans. The organism is shed abundantly from the placental membranes of sheep. Sheep used in reproductive research or other studies should be examined for possible infection. Infected individuals may be treated with antibiotics.

Erysipelas. This disease, found mainly in pigs, can be transmitted as a severe focal skin infection to humans. Symptomatic pigs should be handled with extreme caution.

Rabies. While most cats and dogs used in research studies are vaccinated against rabies, large animals such as cows and horses are not. When working with cattle or horses, pre-exposure rabies prophylaxis is encouraged.

Leptospirosis. See Dogs section (above).

Listeriosis. Listeriosis is a serious disease that can cause meningitis and miscarriages when spread by oral-fecal contamination or by eating products from infected animals. The animals most commonly affected are sheep, cattle, swine and rabbits. A less serious problem is a rash on the hands and arms after direct contact with infectious material.

Brucellosis. See Dogs section (above).

Suggested PPE for individuals handling farm animals: eye protection, fiber facemask, gloves, body covering and shoe covers.

Birds, Skunks, Reptiles or Amphibians.
The following is a list of diseases/agents that are often associated with birds, skunks, reptiles or amphibians:

Rabies. Rabies can be a potential threat in bats and skunks. It is recommended that personnel handling these animals have pre-exposure rabies prophylaxis.

Salmonella. Salmonella is a bacteria frequently harbored in turtles and other reptiles and amphibians. Symptoms of infection include abdominal pain, fever and diarrhea. Transmission usually occurs via mucous membrane or open would exposure.

Psittacosis. This disease is found mainly in birds. All birds used in research should undergo appropriate quarantine and evaluation before being used for research or demonstration purposes.

Listeriosis. See Farm Animals section (above).

Suggested PPE for individuals handling birds, skunks, reptiles or amphibians: eye protection, fiber facemask, gloves, body covering.

Non-human Primates.
The following is a list of diseases/agents that are often associated with NHPs:

Enterics. These infections are caused by various parasites and bacteria and are characterized by abdominal pain, diarrhea, fever and dehydration. Some examples of this are Shigella, giardia and cryptosporidia. Transmission is typically through the oral fecal route. While infections are typically self-limiting, severe illness may develop. A physician should evaluate the personnel with persistent dysentery symptoms.

Cercopithicine herpes virus I (also called Herpes virus simiae, Herpes B, Monkey B or B virus).
The disease is 58-70% fatal in humans. B-virus is a member of the herpes group of viruses that occur naturally in macaques and possibly in other Old World monkeys. Infection with B-virus produces very mild disease in the macaque. Most have no obvious evidence of infection. Some macaques may have vesicles (small blisters) which progress to ulcers in the mouth, on the face, lips or genitals, and/or eye infection. These lesions spontaneously heal after a few days, but the virus typically resides permanently in the macaque and may periodically reactivate and cause ulcerative lesions. These relapses are especially likely to occur when the macaque is stressed (similar to cold sores or fever blisters in humans). During these periods the virus resides in the animal's tissues or body fluids, and may be shed by the macaque to the environment. However, macaques without visible lesion symptoms may also shed the virus, so the Guidelines for Prevention of Herpesvirus simiae (B Virus) Infection in Monkey Handlers[7] should be followed closely at all times when working with NHPs and NHP tissues/fluids. Transmission to humans occurs by exposure to contaminated macaque saliva tissue/fluids of infected macaques. Therefore, those working with macaque neural tissues or fluids are at an increase risk of exposure. The most likely routes of transmission are bites and scratches, however transmission may also occur through cuts or other breaks in the skin, or through direct contact with eyes or mucous membranes when handling infected tissues/fluids. Those at risk on contracting this disease include animal caretakers, laboratory personnel or anyone who is exposed to macaques or macaque tissues/fluids. Persons who are immunosuppressed because of medication or underlying medical conditions may be a higher risk for infection. The risk of acquiring B-virus from macaques is low if proper procedures are followed. Thousands of individuals have handled macaques and macaque tissues or body fluids since human infection with B-virus was first reported and very few cases of human infection have been described. The reasons for such an apparently low rate of transmission may include infrequent B-virus shedding by macaques, neutralizing activity in human sera against B-virus stimulated by herpes simplex virus infection and undetected asymptomatic infection. Given the potential for exposure, the number of reported human cases is very low. However, the majority of identified cases resulted in the development of encephalitis and death. Proper work practices markedly reduce the chances of infection. Symptoms of B-virus infection in humans include:

- Vesicular (small blister)skin lesions at or near the site of injury,
- Localized neurological symptoms such as pain, numbness or itching near the wound site,
- Flu –like aches and pains,
- Fever and chills,
- Headaches lasting more than 24 hours,
- Fatigue,
- Muscular incoordination,
- Shortness of breath, and
- Difficulty in swallowing.

If any symptoms characteristic of B virus occur following an injury involving a macaque, equipment contaminated with their secretions, or macaque tissues or body fluids, immediately report these to the veterinarian on call, and/or the laboratory supervisor and seek medical attention. Symptoms that occur even without overt exposure must be treated the same as a known exposure if there is a risk of infection due to working in macaque areas. An aerosol exposure to the eye could be insidious but just as serious as one where there is a known splash to the eye.

For exposures to the skin (exposure is defined as any possibly fluid to fluid transmission), wash with soap and water continuously for a minimum of 15 minutes with a massaging motion. Examples of skin exposures could be bites, scratches (not necessarily bleeding) and needle sticks. Apply a clean sterile bandage if appropriate. If the exposure occurs in the eye or other mucous membrane, the injury site must be immediately flushed with water for a minimum of fifteen minutes. Notify your supervisor immediately of the incident and fill out the OHSU incident report. You may be asked to speak with an OHSU veterinarian who will evaluate the incident and decide if further measures are required. If a decision is made that a medical professional should evaluate the injury, the worker will be sent to see a physician with a working knowledge of B Virus infections. If an infectious disease specialist is not immediately available, the worker will be sent to a physician and pertinent information about B-Virus will be provided to the physician via the worker or supervisor.

Filoviruses. In humans, the diseases are marked by severe hemorrhagic fever and high death rates. However, human illness has not been associated with occupationally acquired exposures from infected macaques. Stringent procedures are taken to increase the level of worker protection during importation and quarantine of NHPs, particularly cynomolgus, rhesus macaques and African green monkeys. The OHSU NHP quarantine facility and its procedures are routinely inspected by the CDC to assure that the appropriate guidelines for handling of NHPs during transit and quarantine are being followed. OHSU has been in compliance during the inspections, and as a result, OHSU's CDC registration to import NHPs has been continued. Epidemiological and clinical experience with filovirus infection in humans is limited. Preliminary data suggests that the risk of illness is low, however there is a potential that must be considered. Adequate prescribed biosafety procedures should be followed for all tasks involving NHPs.

Simian Immunodeficiency Virus (SIV). SIV has been isolated from the blood, cerebrospinal fluid, and a variety of tissues of infected NHPs, and is antigenically identical to HIV2. Limited data exist on the concentration of virus in semen, saliva, cervical secretions, urine, breast milk and amniotic fluid of infected animals. The skin, especially when scratches, cuts, abrasions, dermatitis or other lesions are present and mucous membranes of the eye, nose and mouth should be considered as potential pathways for entry of SIV. Needles, sharp instruments, broken glass and other sharp objects must be carefully handled and properly discarded. Care must be taken to avoid spilling and splashing infected cell culture media and other virus-containing or potentially infected materials. The CDC recommends a minimum of BSL-2 standards and special practices, containment equipment and facilities for all activities involving blood-contaminated clinical specimens, body fluids and tissues from SIV-infected or inoculated laboratory animals. If a worker has a parenteral or mucous membrane exposure to blood, body fluid or viral culture material, the source material should be identified and, if possible, tested for the presence of virus. If the sources material is positive for SIV antibodies, virus or antigen, or is not available for examination, the worker will be counseled regarding the risk of infection and will be evaluated clinically and serologically for evidence of SIV infection. The worker will be advised to report and seek medical evaluation of any febrile illness that occurs within 12 weeks after exposure. Such an illness, particularly one characterized by fever, rash or lymphadenopathy, may indicate recent infection. If seronegative, the

worker should be retested 6 weeks after the exposure and periodically thereafter (i.e., at 12 weeks and 6, 9, and 12 months after exposure) as recommended by the attending physician.

Tuberculosis. NHPs are more susceptible to TB than healthy immunocompetent people. However, naturally infected NHPs, or tissues/body fluids from these animals, are potential sources for human infection. Precautions include TB testing programs in NHPs and humans, protective clothing and personal hygiene. Symptoms of an active TB infection include:

- Weight loss
- Fatigue
- Malaise
- Fever/night sweats
- Coughing with thick sputum, possibly bloody
- Chest pain when breathing or coughing
- Cough that lasts longer than 2 weeks

This disease is aerosol transmissible and presents a considerable risk to both the human and NHP populations. Individuals who have access to NHP housing are routinely monitored for the presence of TB.

Measles. An unvaccinated NHP population is at risk for contracting measles from humans. Most individuals have had previous exposure to or vaccination against measles, so infection of the NHP population is not viewed as a significant risk at this time. Symptoms of an active measles infection include:

- Running nose
- Cough
- Slight fever
- Eyes redden and become sensitive to light
- Fever that rises over time to a peak of 103F – 105F
- Red blotchy skin rash starting at the face and eventually spreading over the entire body
- White spots can occur inside of the mouth on the gums and the cheeks (Koplik spots)

The disease is communicable by direct contact with fluids from the nose or mouth, and therefore can be aerosol transmissible and very contagious to NHP populations. Individuals with symptoms of measles should not share airspace with NHPs.

Appropriate PPE must be worn in all NHP housing rooms. When physically working with NHPs, including cleaning and care activities, wear the following:

1. Disposable coveralls with full-length sleeves (limited exposure may allow use of disposable gowns with full-length sleeves),
2. Fiber face mask or surgical mask that covers the nose and mouth,
3. Eye protection (prescription or non-prescription wrap-around safety glasses or goggles),
4. Latex or nitrile gloves,
5. Appropriate leather gauntlet gloves when restraining NHPs, and

6. Appropriate Kevlar forearm protection when performing tasks where there is close contact with the NHPs.

When entering NHP housing or use rooms, but not actually handling NHPs, the following should be worn:

1. Uniform coveralls, nylon water resistant overgarments or blue lab coat,
2. Fiber face mask,
3. Latex gloves, and
4. Eye protection (prescription or non-prescription wrap-around safety glasses or goggles).

Special considerations: Wear appropriate protective clothing. Work with at least one other person when handling NHPs. Minimize direct handling. Report any observed facial, lip or oral lesions in NHPs to a staff veterinarian. Immediately report all bites or scratches direct from the live animal, contaminated needle/sharps sticks and mucous membrane exposures involving macaques. Also report any injury involving macaque tissues or body fluids that are associated with breaks in the skin or mucous membranes.

4.4 Laboratory Animal Allergens

Allergic reactions associated with handling animals are common in the home and can also occur at the workplace. The potential for animal-care workers to develop allergic symptoms has been clearly demonstrated[8]. Studies have also shown that animal care workers with preexisting allergic conditions, such as hay fever, are more likely to develop sensitivity to animal related allergens at work[9]. Symptoms can even evolve into occupationally –related asthma.

Animal allergens are usually a protein or glycoprotein. These materials are most often associated with urine or dander from a specific animal. The most common route of exposure is airborne, although skin and gastrointestinal tract exposures can also lead to an allergic reaction. The human immune system produces antibodies that are specific for each allergen as a result of initial exposures. During subsequent exposures, the allergen binds with these antibodies causing the release of histamines stored in cells closely associated with the antibodies. These chemicals, on contact with the surrounding tissue (respiratory tract, etc.) can result in hives, nasal congestion, sneezing, nasal drainage, coughing, wheezing and shortness of breath. These symptoms can occur as quickly as 10-15 minutes after exposure. Rats, mice, guinea pigs, gerbils, rabbits, cats and dogs have all been shown to be sources of allergen exposure to laboratory animal workers. However, NHPs have rarely been found to cause sensitization. The major sources of allergens in rats and mice appear to be urine and saliva. Guinea pigs also produce allergenic materials in dander, fur, saliva and urine, with urine appearing to be the major source. Rabbits produce a glycoprotein allergen that is primarily associated with the fur, although saliva and urine allergens do exist.

The primary exposure route for workers is inhalation. Disturbance of contaminated litter and bedding results in the release of very small particles of litter containing the allergen. These particles are often small enough to stay airborne for extended periods of time and can easily be deposited in the airway. Studies have demonstrated that cage cleaning, weighing, shaving, injections, blood collection and surgery can release significant quantities of the allergens[10]. Of these, cage cleaning represents a major

source of exposure. However, the ultimate magnitude of exposure is directly proportional to the number of animals in a given work area. General ventilation may or may not be effective.

Almost everyone knows someone who is allergic to cats or dogs. The major cat allergen is produced by the sebaceous glands in the skin and coats the hair shaft. It is also produced in the saliva. Airborne particles containing this allergen can remain suspended for long periods because of their very small size. Consequently, respiratory exposure is common. These particles also have a tendency to adhere to surfaces such as walls and laboratory benches, making it easy to transfer to hands. Although dogs have not been studied as extensively as cats, an important allergen has been identified. The main sources of this allergen appear to be saliva, hair and skin.

Thoughtful job assignment, careful work practices and training can serve to reduce the release of allergens and thus reduce the potential for exposure. Workers with known risk can be assigned to tasks with low risk of exposure to allergen. For example, tasks such as feeding and weighing result in low levels of exposure. Task assignment is the first important step in minimizing exposures, especially for workers who have become sensitized. Minimizing exposure time in animal housing areas with potential for allergen release is another approach to reducing exposure. More important is to minimize manipulation/disturbance of animal litter and bedding after contamination.

PPE should be utilized in addition to engineering controls to reduce the potential for exposure. At a minimum, workers should wear dedicated lab coats, disposable gowns or coveralls, latex gloves and eye protection. In addition, a HEPA filtered dust/mist disposable respirator should be worn by individuals with known animal related allergies at all times while in the animal housing area. Before using any type of respirator contact EHRS. Hands and exposed skin areas should be washed prior to leaving the area.

All personnel should receive instruction prior to entering animal housing areas where allergen exposure is likely. Training should include at a minimum the following topics:

1. Animal allergen theory
2. Specific animals of concern
3. Symptoms
4. Work practices
5. PPE

V. OCCUPATIONAL HEALTH PROGRAM

5.1 The OHSU Occupational Health Program

All OHSU employees are included in the Occupational Health Program. TB screening by the Employee Health Department or Student Health Services is:

1. Required upon hire or commencement of duty or schooling for all persons. Two step skin testing is required if a TB skin test has not been applied within the last twelve (12) months and the individual has no history of a positive skin test.
2. Required annually for persons who:

- Have face-to-face contact with patients, or human or primate research subjects,
- Handle respiratory secretions from humans or primates, or
- Have a history of a positive skin test.

The purpose of TB screening is for the protection of the NHP colony. TB testing is repeated at least annually for those having access to NHP housing areas. Individuals who do not participate in the Occupational Health Program will not be allowed access to animal areas. When appropriate, pre-exposure rabies vaccine, hepatitis B, hepatitis A, and Q-fever testing is provided. Other vaccinations provided include tetanus, varicella, meningococcus, pneumococcus, measles, mumps, smallpox and rubella.

5.2 Specific Bloodborne Pathogens: Human Tissues/Body Fluids

A number of researchers at OHSU currently work with human tissues and/or body fluids. A variety of pathogens can reside in human tissues/body fluids. There are many reports concerning laboratory-associated infections while working with these materials[4]. Many of these instances were associated with research or clinical work focused on a specific infectious agent. BMBL[1] and Pike[4] provide excellent references on agents that have been reported to cause disease in laboratory workers. It is not the intent of this manual to create an exhaustive list of all pathogens that have the potential to cause laboratory-associated disease as a result of work involving human tissues/body fluids. However, there are some primary agents of concern, which include the following:

Hepatitis B Virus. This virus can be present in blood, urine, semen, cerebrospinal fluid, saliva and tissues. Transmission is typically via accidental inoculation or direct exposure of mucous membranes or compromised skin to infectious material. All human tissues/body fluids should be handled with universal precautions to reduce the potential for exposure. The virus is quite stale and has been shown to survive several days in dried blood. Symptoms of infection may or may not be present. Symptoms may include fatigue, nausea, weakness, headache, chills, jaundice and liver disease. Currently in the U.S., there are approximately 5,000 deaths per year attributed to HBV infection. A prophylactic immune globulin and recombinant vaccine are both available.

In compliance with 29 CFR 1910.103(f), OHSU will make the HBV vaccine and vaccination series available to all OHSU employees who have potential occupational exposure to human tissues/body fluids, and post-exposure evaluation and follow-up to all employees who have an exposure incident involving human tissues/body fluids. An exposure incident is an incident that involves eye, mouth, other mucous membrane, non-intact skin or parenteral contact with human tissues/body fluids. All medical evaluations, procedures and laboratory tests associated with the vaccine and any exposure incidents will be provided at no cost to the employee and will be confidential. This medical treatment will be performed by or under the supervision of a licensed physician or another licensed health care professional and will be provided according to recommendations of the U.S. Public Health Service current at the time these evaluations and procedures take place.

HBV vaccination will be made available after each employee has received the bloodborne pathogen training, and within 10 working days of initial assignment, to all employees who have occupational exposure unless the employee has previously received the complete HBV vaccination series, antibody

testing has revealed that the employee is immune, or the vaccine is contraindicated for medical reasons. If the employee initially declines HBV vaccination, but at a later date decides to accept the vaccination, the vaccination series will be made available. All employees who decline to accept the HBV vaccination must sign a vaccine declination statement. If a routine booster dose of HBV vaccine is recommended by the U.S. Public Health Service at a future date, such booster dose(s) will be made available.

Hepatitis C Virus. HCV is very similar to HBV in potential transmission routes and symptoms. All human tissues or fluids should be handled under universal precautions. According to the CDC, there are more cases of hepatitis C (10,000 deaths per year) than hepatitis B. By the time most cases are diagnosed, there is irreversible liver damage. There is no vaccine for HCV and treatment options are limited at this time.

Human Immunodeficiency Virus (HIV). Over one million Americans are believed to be seropositive for this retrovirus, yet very few are believed to have seroconverted due to occupational exposure. Of those cases, the most common means of transmission appears to have been percutaneous inoculation, direct mucous membrane exposure, and direct exposure of non-intact skin to infected body fluids or tissues. The cell-associated nature of the virus appears to limit the potential for airborne exposure. HIV has been found in blood, semen, saliva, tears, urine, cerebrospinal fluid, amniotic fluid, breast milk, vaginal secretions, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, and a number of different tissues. The virus appears to be quite fragile and succumbs quickly to drying and chemical disruption[11].

5.3 Post-Exposure Evaluation and Follow-up

Any direct contact with human or animal tissues or fluids could be considered a potential exposure. The route(s) of exposure and the circumstances under which the exposure incident occurred will be documented for all exposure incidents. The source individual will be identified and documented unless such identification is not feasible. The source individual's blood will be tested as soon as feasible and after consent is obtained in order to determine HCV, HBV and HIV infectivity. If consent is not obtained, OHSU will establish that legally required consent cannot be obtained. When the source individual's consent is not required by law, the source individual's blood, if available, will be tested and the results documented. When the source individual is already known to be infected with HCV, HBV or HIV, testing for the source individual's known HCV, HBV or HIV status need not be repeated. Results of the source individual's testing will be made available to the exposed employee, and the employee will be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual. The exposed employee's blood will b e collected as soon as feasible and tested after consent is obtained. If the employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, the sample will be preserved for at least 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing will be done as soon as feasible. If medically indicated, post-exposure prophylaxis will be offered at no expense to the employee. Counseling and evaluation of reported illnesses will also be made available to the exposed employee.

OHSU will obtain and provide the exposed employee with a copy of the evaluating health care professional's written opinion. The health care professional's written opinion for HBV vaccination will be limited to whether HBV vaccination is indicated for the employee and if the employee has received such vaccination. The health care professional's written opinion for post-exposure evaluation and follow-up will be limited to documenting that the employee has been informed of the results of the evaluation and

about any medical conditions resulting from exposure to blood or OPIM which require further evaluation or treatment. All other medical findings or diagnoses will remain confidential and will not be included in the written report.

5.4 Information Provided to the Health Care Professional

OHSU will ensure that the health care professional evaluating an employee after an exposure incident is provided the following information:

1. A copy of OAR 437-003-0360/29 CFR 1910.1030.
2. A description of the exposed employee's duties as they relate to the exposure incident.
3. Documentation of the routes(s) of exposure and circumstances under which exposure occurred.
4. Results of the source individual's blood testing, if available.
5. All medical records relevant to the appropriate treatment of the employee, including vaccination status.

5.5 HIV and SIV Laboratory/Animal Care Hazards and Statistics

This section is devoted to the characteristics of HIV and SIV, as well as the primary laboratory/animal care hazards of working with these agents.

Data on occupational HIV transmission in laboratory workers were collected through two CDC-supported national surveillance systems, a surveillance for AIDS and a surveillance for HIV-infected persons who may have acquired their infection through occupational exposures. For these purposes, laboratory/animal care workers are defined as those persons, including students and trainees, who have worked in a clinical or research HIV laboratory/animal care setting at anytime since 1978. Persons reported from these two systems are classified as cases of either documented or possible occupational transmission. Those classified as documented occupational transmission had evidence of HIV serconversion (a negative HIV-antibody test at the time of exposure which converted to positive) following a discrete percutaneous or mucocutaneous occupational exposure to blood, body fluids or other clinical or laboratory specimens. Thos persons classified as possible occupational transmission do not have behavioral or transfusion risks for HIV infection which could be identified during follow-up investigation, and each reported past percutaneous or mucocutaneous occupational exposures to blood, body fluids or laboratory specimens, but seroconversion to HIV was not documented. Among those with documented occupational transmission, the great majority had percutaneous or mucocutaneous exposures. The three non-clinical exposures involved exposure to concentrated virus in a laboratory.

In 1992, two workers were reported to have developed antibodies to SIV following exposures in different laboratories. One was associated with a needle stick, which occurred while the worker was manipulating a blood-contaminate needle after bleeding an SIV-infected macaque monkey. The other involved a laboratory worker who handled macaque SIV-infected blood specimens without gloves. Although no specific incident was recalled, this worker had dermatitis on the forearms and hands while working with the infected blood specimens. As of this writing neither of the two workers has developed any illness.

HIV has been isolated from blood, semen, saliva, tears, urine, cerebrospinal fluid, amniotic fluid, breast milk, cervical secretion and tissue of infected persons and experimentally infected NHPs. The CDC has recommended that universal precautions be observed when handling human blood and body fluids or blood and body fluid from experimentally infected NHPs. Although the risk of occupationally acquired HIV is primarily through exposure to infected blood, it is also prudent to wear gloves when manipulating other body fluids such as feces, saliva, urine, tears, sweat and vomitus from humans or experimentally infected NHPs. This reduces potential exposure to low levels of HIV as well as microorganisms that may cause other types of infections. In the laboratory, HIV should be presumed to be present in all blood or clinical specimens contaminated with blood, in any unfixed tissue or organ (other than intact skin) from a human or experimentally infected NHP (living or dead), in HIV cultures, in all materials derived from HIV cultures and in/on equipment and devices coming into direct contact with any of these materials.

SIV has been isolated from blood, cerebrospinal fluid, and a variety of tissues of infected NHPs. Limited data exist on the concentration of virus in semen, saliva, cervical secretions, urine, breast milk and amniotic fluid of infected animals. In the laboratory, virus should be presumed to be present in all SIV cultures and in animals experimentally infected or inoculated with SIV cultures, in all materials derived from SIV cultures and in/on all equipment and devices coming into direct contact with any of these materials. The skin (especially when scratches, cuts, abrasions, dermatitis or other lesions are present) and mucous membranes of the eye, nose and mouth should be considered as potential pathways for entry of SIV. Needles, sharp instruments, broken glass and other sharp objects must be carefully handled and properly discarded. Care must be taken to avoid spilling and splashing infected cell-culture media and other virus-containing or potentially infected materials.

The CDC recommends a minimum of BSL-2 standard and special practices, containment equipment and facilities for all activities involving all blood-contaminated clinical specimens, body fluids and tissues from all humans or from HIV- or SIV-infected or inoculated laboratory animals. Activities such as producing research-laboratory-scale quantities of HIV or SIV, manipulating concentrated virus preparations, and conducting procedures that may produce droplets or aerosols, are performed in a minimum of a BSL-2 facility, but using the additional practices and containment equipment recommended for BSL-3 facility, using BSL-3 practices and containment equipment. NHPs or other animals infected with HIV or SIV should be housed in a minimum of ABSL-2 facilities using ABSL-2 special practices and containment equipment.

There is no evidence that laboratory clothing poses a risk for HIV or SIV transmission. However, clothing that becomes contaminated with HIV or SIV preparations, or secretions from experimentally infected animals should be decontaminated before being laundered or discarded. Laboratory/animal care personnel must remove protective clothing before going to non-containment areas. Work surfaces are to be decontaminated with an appropriate chemical germicide after procedures are completed, when surfaces are overtly contaminated and at the end of each workday, if used that day. Many commercially available chemical disinfectants can be sued for decontaminating laboratory/animals areas and some laboratory instruments, for spot cleaning of contaminated laboratory clothing and for spills of infectious materials. Prompt decontamination of spills should be standard practice.

If a laboratory/animal care worker has a parenteral or mucous membrane exposure to blood, body fluid or viral culture material, the source material should be identified and, if possible, tested for the presence of virus. If the source material is positive for HIV/SIV antibodies, virus or antigen, or is not available for examination, the worker will be counseled regarding the risk of infection and will be evaluated clinically and serologically for evidence of HIV/SIV infection. The worker will be advised to

report and seek medical evaluation of any febrile illness that occurs within 12 weeks after exposure. Such an illness, particularly one characterized by fever, rash or lymphadenopathy, may indicate recent HIV infection. If seronegative, the worker should be retested 6 weeks after the exposure and periodically there after (i.e., at 12 weeks and 6, 9 and 12 months after exposure) as recommended by the attending physician.

Other primary and opportunistic pathogenic agents may be present in the body fluids and tissues of persons/animals infected with HIV/SIV. Laboratory/animal care workers must follow SOPs based on accepted biosafety practices to ensure maximum protection against inadvertent exposure to agents that may also be present in clinical specimens or in specimens/wastes obtained from NHPs.

5.6 Prions

Prions are proteinaceous infectious particles that lack nucleic acids. In mammals, prions are composed of an abnormal, pathogenic isoform of the prion protein (PrP), designated Prp^{Sc}. The "Sc" superscript was initially derived from the term scrapie because scrapie is the prototypic prion disease. The name scrapie was derived from the observation that affected animals rubbed against the fences of their pens to stay upright, presumably reflecting the manifestation of ataxia. Transmissibility was accidentally but stunningly demonstrated in 1943 when a population of Scottish sheep was inoculated against a common virus with a formalin extract of lymphoid tissue unknowingly derived from an animal with scrapie after two years, nearly 10% of the flock developed scrapie. Since all of the known diseases of mammals involve aberrant metabolism of PrP similar to that observed in scrapie, use of the "Sc" superscript is suggested for all abnormal, pathogenic PrP isoforms. The prion diseases are also referred to as the transmissible spongiform encephalopathy or TSEs.

Table 2

Disease (abbreviation)	Natural Host	Prion	Pathogenic PrP Isoform
Bovine spongiform encephalopathy (BSE)	Cattle	BSE prion	$BoPrP^{Sc}$
Chronic wasting disease (CWD)	Mule deer, elk	CWD prion	$MdePrP^{Sc}$
Creutzfeldt-Jakob disease (CJD)	Humans	CJD prion	$HuPrP^{Sc}$
Exotic ungulate encephalopathy (EUE)	Nyala, greater kudu	EUE prion	$UngPrP^{Sc}$
Fatal familial insomnia (FFI)	Humans	FFI prion	$HuPrP^{Sc}$
Feline spongiform encephalopathy (FSE)	Cats	FSE prion	$FePrP^{Sc}$
Gerstmann-Sträussler-Scheinker syndrome (GSS)	Humans	GSS prion	$HuPrP^{Sc}$
Kuru	Humans	Kuru prion	$HuPrP^{Sc}$
Scrapie	Sheep, goats	Scrapie prion	$OvPrP^{Sc}$
Transmissible mink encephalopathy (TME)	Mink	TME prion	$MkPrP^{Sc}$

Human prions and those propagated in apes and monkeys are manipulated at BSL 2 or 3, depending on the studies being conducted. BSE prions are likewise manipulated at BSL 2 or 3, due to the possibility that BSE prions have been transmitted to humans in Great Britain and France. The absence of any known effective treatment for prion disease demands caution. The highest concentrations of prions are in the central nervous system and its coverings. Based on animal studies, it is likely that high

concentrations of prions are also found in spleen, thymus, lymph nodes, and lung. The main precaution to be taken when working with prion-infected or contaminated material is to avoid puncture of the skin. If accidental contamination of skin occurs, the area is swabbed with In sodium hydroxide (NaOH) for 5 minutes and then washed with copious amounts of water. Unfixed samples of brain, spinal cord, and other tissues containing human prions should be processed with extreme care at BSL 3.

Prions are characterized by extreme resistance to conventional inactivation procedures including irradiation, boiling, dry heat, and chemicals (formalin, betapropiolactone, alcohols). Sterilization of rodent brain extracts with high titers of prions requires autoclaving at 132C for 4.5 hours. Denaturing organic solvents such as phenol or chaotropic reagents such as guanidine isothiocyanate or alkali such as NaOH can also be used for sterilization. Disposable plasticware, which can be discarded as a dry waste, is highly recommended.

Although there is no evidence to suggest that aerosol transmission occurs in the natural disease, it is prudent to avoid the generation of aerosols or droplets during the manipulation of tissues or fluids and during the necropsy of experimental animals. Formaldehyde-fixed and paraffin-embedded tissues, especially of the brain, remain infectious. Some investigators recommend that formalin-fixed tissues from suspected cases of prion disease be immersed for 30 min in 96% formic acid or phenol before histopathologic processing, but such treatment may severely distort the microscopic neuropathology.

The diseases are characterized by loss of motor control, dementia, paralysis wasting and eventually death, typically following pneumonia. Details of pathogenesis are largely unknown. However, evidence indicates that the responsible protein arrives at a pathogenic state by misfolding from a normal form that has ubiquitous tissue distribution.

While most CJD cases are sporadic in occurrence, autosomal-dominant transmission accounts for 10% of cases. Particularly notable have been cases of transmission between humans iatrogenically, through transplantation of infected corneas or injection of growth hormone derived from human pituitaries. Even more striking have been a number of early-onset CJD cases with atypical pathology recently reported from Great Britain suggested to have been transmitted by consumption of meat from cows suffering from mad cow disease, a spongiform encephalopathy recently epidemic in British herds. Reports of the ability to produce disease clinically and pathologically similar CJD in macaques by intracerebral injection of brain homogenate from afflicted cows, and of biochemical properties shared between the human cases and bovine spongiform encephalopathy (BSE), suggest that BSE is transmissible to man.

5.7 NHP Exposure Procedures – West Campus

These procedures apply to <u>all</u> skin breaking or mucous membrane exposures received from NHPs, injuries inflicted while handling <u>contaminated</u> NHP used equipment such as cages, needles and other sharps, and injuries involving NHP tissues and body fluids when these injuries or wounds penetrate the skin.

For superficial or minor wounds that break the skin and cause bleeding, and for eye or nasal/mouth exposures that are directly associated with <u>macaques</u> or laboratory manipulation of <u>macaque</u> tissues or

body fluids but are not life-threatening, including bites, scratches, contaminated needle/sharps sticks and all mucous membrane exposures.

Exposure Procedures for OHSU West Campus For any **life threatening** emergency, ensure your own safety then call **9-911**. After calling 9-911, notify the ONPRC switchboard at 503-690-7777.

For any non human primate tissue or fluid exposure:

1. Wash the wound immediately with soap and water for 15 minutes using a massaging motion to make the wound bleed. For mucous membrane exposures, rinse the area for 15 minutes with running water.
2. Contact the Veterinarian on call. The on call schedule is located on the J: drive under "Vet on Call" and posted in key areas on the campus.
3. After consultation with the vet on call, contact the Medical Technologist at 503-690-5216 for a blood sample.
4. Call Infectious Disease Consultants at the Providence Medical Center 503-216-7000 and inform them of the exposure and the need for a medical evaluation appointment. Report to the facility, located at 9155 SW Barnes Road., Suite 931, Portland, OR. Be sure to take the "Personnel Animal Exposure Procedure" form from the vet on call with you to the appointment.
5. For exposures during evenings and weekends that require a medical evaluation, report to St. Vincent Hospital Emergency Room at 9205 SW Barnes Road, Portland, OR, 97225. Be sure to take the "Personnel Animal Exposure Procedure" form from the vet on call with you to the appointment. The next working day, contact the campus Medical Technologist at 503-690-5216 to obtain a blood sample.
6. Complete the front of the incident report form and forward it to your supervisor. Incident report forms are located at: http://ozone.ohsu.edu/ehrs/wc/pages/gen/acc.shtml.
7. Supervisors should complete the back of the incident report form and forward it to the ONPRC Human Resources Department.
8. Within 48 hours of the incident, contact the ONPRC Human Resources Department to complete the workers compensation claim.

5.8 Other Occupational Related Injury or Illness Reporting Procedures

West Campus:

1. Wash the area thoroughly with soap and water. Use only water if it is a mucosal area.
2. Notify your supervisor of the incident.
3. If medical attention is necessary, contact either your primary care physician or report to Cascade Occupational Medicine at Tuality Health Place, 1200 NE 48th Ave Ste 700, Hillsboro, OR 97214, 503-726-1021. Be sure to inform the provider that the injury is work related and a workers compensation form 801 should be completed and submitted to OHSU Risk Management.
4. Complete the front of the incident report form and forward it to your supervisor. Incident report forms are located at: http://ozone.ohsu.edu/ehrs/wc/pages/gen/acc.shtml.
5. Supervisors should complete the back of the incident report form and forward it to the ONPRC Human Resources Department.
6. Contact the ONPRC Human Resource Department to complete the workers compensation claim.

Central & Waterfront Campus:

1. Wash the area thoroughly with soap and water. Use only water if it is a mucosal area.
2. Notify your supervisor of the incident.
3. If medical attention is necessary, contact either your primary care physician or report to the OHSU Emergency Room. Be sure to inform the health care provider that the injury is work related.
4. Complete an incident report form and forward to your supervisor.
5. Contact the Risk Management Department regarding completing a works compensation claim.

VI. MEDICAL WASTE MANAGEMENT

6.1 Definition of Medical Waste

Medical waste management has developed into a controversial issue in recent years. This controversy has resulted in a number of groups evaluating the public and occupational risk associated with waste emanating from medical settings. Medical waste is waste that has been generated as a consequence of patient diagnosis, treatment or immunization as well as waste associated with laboratory manipulation of human or animal tissues or body fluids. Medical waste may or may not be infectious waste. Infectious waste is viewed as a subset of medical waste. More specifically, infectious waste is that part of medical waste that has been shown to transmit disease to humans.

In the state of Oregon, the legal definition of infectious waste is presented in Chapter 763, Oregon Laws, 1989 and Oregon Administrative Rules (OAR) 333-18-040 trough 070[12]. According to OAR, infectious waste means:

1. Biological waste, which includes blood and blood products , excretions, exudates, secretions, aspirates and other body fluids that cannot be directly discarded into the municipal sewer system, and waste materials saturated with blood or body fluids, but does not include diapers soiled with urine or feces. In addition, biological waste does not include articles contaminated with fully absorbed or dried blood, such as gauze, paper towels and sanitary napkins.
2. Cultures and stocks, which includes etiologic agents and associated biologicals, including specimen cultures, dishes and devices used to transfer; inoculates and mix cultures, wastes from production of biologicals, serums that have not been decontaminated and discarded, live and attenuated vaccines. This does not include throat and urine cultures.
3. Pathological waste, which includes biopsy materials and all human tissues, anatomical parts that emanate from surgery, obstetrical procedures, autopsy and laboratory procedures and animal carcasses exposed to pathogens in research and the bedding and other waste from such animals. Pathological waste does not include teeth or tissue that is fixed with formaldehyde or other preservative agents.
4. Sharps, which includes needles, IV tubing with needles attached, scalpel blades, lancets, glass tubes that could be broken during handling, and syringes, with and without needles, that are either clean or contaminated.

Note that the definition of infectious waste does not include contaminated solid waste (paper, paper towels, table liner, latex gloves, various plastics), as described in #1, unless the item is saturated with blood or body fluids [13]. The term fully absorbed is interpreted to mean not dripping or not capable of

releasing blood or body fluids if compressed. The reason for this is that the only medical waste that has been proven to be associated with infectious disease transmission is contaminated sharps[14]. Also note that tissue from animals is legally classified as infectious waste only if the animal has been experimentally exposed to human pathogens.

6.2 Autoclave Use and Requirements

OHSU requires that certain materials and items be autoclaved before leaving their location of generation and entering the waste stream to be incinerated. All autoclave users must develop standard protocols for proper autoclave performance as described in Oregon Health Division regulation OAR 333-18-060(2)(b). The following items should be autoclaved or chemically disinfected before disposal.

1. Animal tissues not meeting the definition of pathological waste.
2. Infectious agents not meeting the definition of cultures and stocks, propagated experimental agents and any agents isolated from animals.
3. Specific contaminated solid waste to be autoclaved is limited to the containers and transferring devices used in procedures associated with #1 and #2 above.
4. Materials saturated with body fluids, tissue culture fluids and other material as previously discussed.

6.3 Segregation of Infectious Waste

Infectious wastes must be segregated from other wastes by separate containment at the point of generation. Storage enclosures used for infectious wastes need to be secured to prevent access by unauthorized persons and must be marked with the universal biohazard symbol.

6.4 Medical Waste Stream Procedures

Medical waste generation at OHSU differs slightly by each specific area. This manual was written provide guidelines for prudent medical waste handling practices and to comply with local, state and federal regulations. It is the intent of this section to provide guidelines to help make decisions that are prudent and comply with these regulations. The specialized needs of a given laboratory or animal area may require additional evaluation of medical waste handling procedures. For assistance with questions regarding waste handling procedures, contact EHRS.

Sharps (glass pipettes, serum tubes, syringes, needles, etc.) must be placed in rigid sharps containers immediately after use. In the rare circumstance where it is not possible to immediately place sharps into sharps containers, temporary container may be used provided that no personnel exposure to the sharps can occur during the eventual transfer to a sharps container. Sharps containers must be sealed when they become no more than ¾ full and a new sharps container provided.

Liquid wastes (media, counting fluid, washes, etc,) should be autoclaved if necessary (see autoclave use and requirements for more details) and discarded into the sanitary sewer.

Solid or semisolid tissues should be placed in labeled bags and transported to the designated collection point for the area. Animal carcasses should be placed in an appropriately labeled bag, refrigerated of frozen as appropriate, and transported to the designated collection point for the area.

Contaminated solid waste (paper towels, bench liner, Tyvek gowns, latex gloves, plastic tubes, pipettes, pipette tips, flasks, etc.) may be autoclaved if appropriate and discarded in the normal solid waste stream. Any color bag may be used for disposal of trash except red. USE RED BAGS FOR BIOHAZARD WASTE ONLY! Those items that are not required to be autoclaved are also to be bagged in non-red bags and placed in the normal solid waste stream.

6.5 Labels and Signs

Biohazard warning labels must be affixed to containers of infectious waste, refrigerators and freezers containing tissue or body fluids, and other containers used to store, transport or ship tissue and body fluids. All labels must include the universal biohazard symbol. When appropriate, red bags or red containers incorporating the universal biohazard symbol may be substituted for labels. Biohazard signs should be posted on the entrances to areas that contain potentially infectious materials.

6.6 Transporter Requirements

Each entity that transports infectious material must:

Provide written certification to OHSU that such waste will be disposed of in compliance with the provisions of the Infectious and Pathological “Waste Act of the State of Oregon enacted in 1989.
Maintain records showing the point of origin and the date and place of final disposal of infectious wastes collected. A copy of this manifest will be maintained at the facility generating the material.

VII. IMPORTATION, INTERSTATE SHIPMENT AND RECEIPT OF HUMAN ETIOLOGICAL AGENTS

This section includes information on importation, interstate shipment and receipt of known etiological agents as well as human and animal tissues/body fluids that may contain human pathogens. All infectious agents transported to or from OHSU should be performed in a safe manner and in compliance with all applicable regulations. The transportation of infectious agents is regulated by both state and federal agencies. Regulations regarding the ground shipment of these agents are detailed in 49 CFR 171-180 and are enforced by the Department of Transportation (DOT). Materials transported by air must comply with International Air Transport Association (IATA) regulations as enforced by the Federal Aviation Administration. In addition, specific permits, such as those from the CDC or the United States Department of Agriculture (USDA), may be required. All NHP tissue that is shipped out of the country must conform with CITES regulations. Contact EHRS for more information on the permitting process.

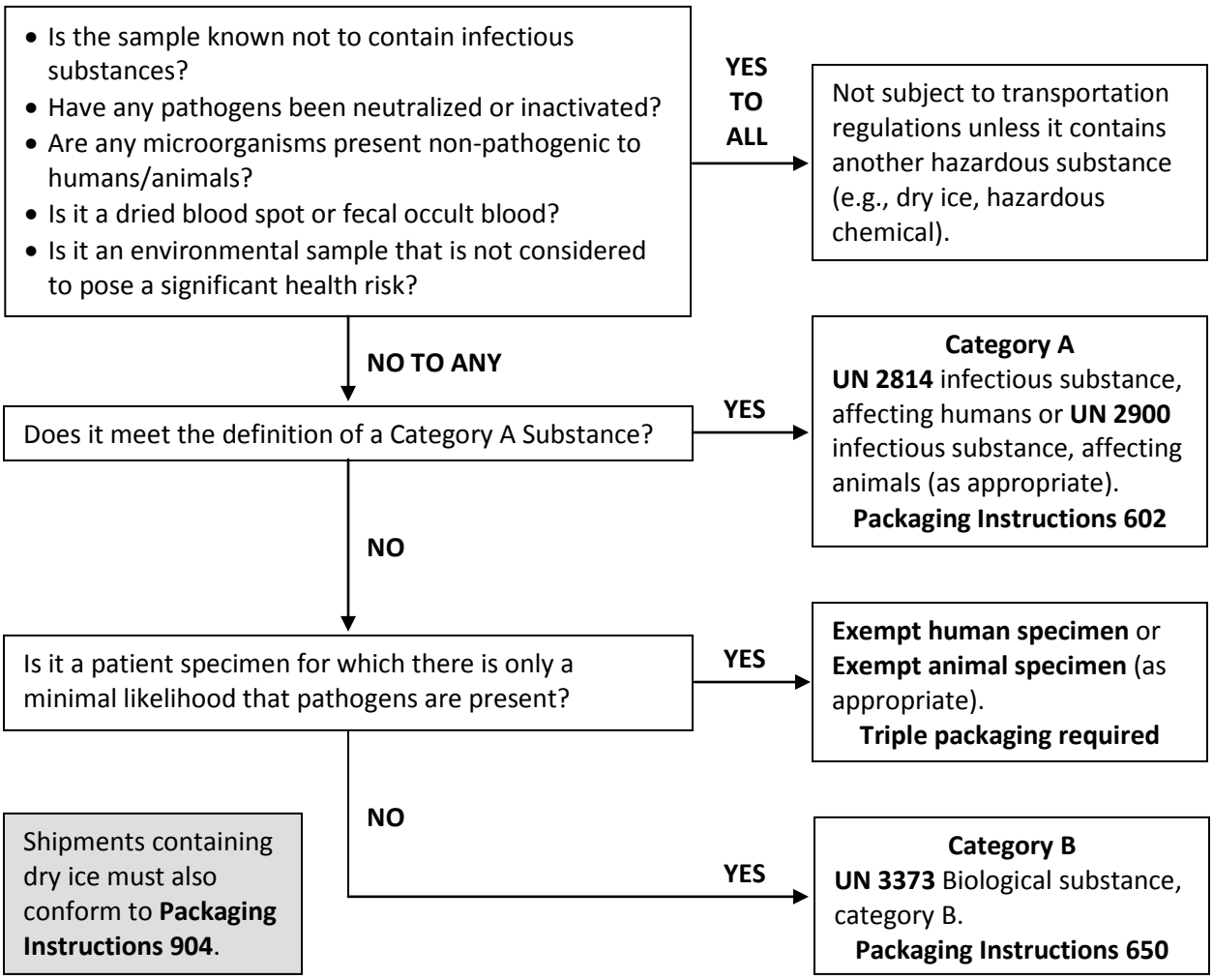
Before a hazardous material is offered for transportation, all relevant persons involved in the preparation of samples for transportation must have received the appropriate training. To ship a biological sample, a worker must be trained in IATA regulations. In addition, the worker will need to know the transporter's own specific requirements. Training is offered at OHSU and is necessary for any worker shipping biological, chemical or radioactive samples, particularly if any samples fall into the Dangerous Goods category. A fine may be levied against individuals who improperly prepare and/or ship a sample. Online training is available on the EHRS website. Training records must be made available upon request to appropriate inspecting agencies. Refresher training must take place within 24 months of previous training to ensure that knowledge is current.

7.1 Hazardous Materials Transportation Guidelines

Numerous accidents occur involving the transportation of hazardous materials. These include accidents involving biological tissues and fluids. All hazardous materials must be transported in accordance with local, state and federal regulations. Biological agents should be brought to designated, trained employees for assistance with proper hazard determination, classification, packaging, labeling, marking and documentation. Only designated, trained individuals are authorized to prepare items classified as Dangerous Goods for shipment. Contact EHRS for more information.

Some materials may not meet the definition of a Dangerous Good, but may still require special packaging and shipping procedures. Examples of materials in this category include biological samples or diagnostic specimens that are not likely to cause disease in humans or animals. A flow chart is provided on the next page as a guide to transporting hazardous materials.

BIOLOGICAL SUBSTANCE TRANSPORTATION FLOW CHART



Additional information, including all relevant packaging instructions and a list of Category A agents, is available in the Biological Safety Training section of the EHRS website, or by contacting the campus BSO.

VIII. DECONTAMINATION

8.1 Purpose and Methods of Decontamination

Contamination is the introduction of microorganisms into tissues or sterile materials. Decontamination is disinfection or sterilization of infected articles to make them suitable for use (reduction of microorganisms to an acceptable level). Disinfection is the selective elimination of certain undesirable microorganisms in order to prevent their transmission. Disinfection reduces the number of infectious

organisms below the level necessary to cause infection. Sterilization is the complete killing of all organisms.

Decontamination methods have always played a role in the control of infectious diseases. However, the most efficient means of rendering infectious diseases harmless (i.e., toxic chemical sterilization) may not be utilizable if harm to people or damage to materials is to be avoided. Mechanical decontamination involved measures to remove, but not necessarily neutralize an agent. An example would be filtration of water to remove *giardia*. Chemical decontamination renders agents harmless by the use of disinfectants, which are usually in the form of a liquid, gas or aerosol. Chemical disinfectants can be harmful to humans, animals, the environment and/or materials. Rooms in fixed places are best decontaminated with gases or liquids in aerosol form (e.g., formaldehyde, vaporized hydrogen peroxide). This is usually combined with surface disinfectants to ensure complete decontamination.

Autoclaving is a physical means of rendering an agent harmless through heat and steam exposures. As a general rule, autoclaving should be done at 121° C/250° F for a minimum of 20 minutes at one atmosphere of overpressure (15 lbs. per square inch), depending on the size and density of the load. Dry heat is another physical means of rendering agents harmless. Exposing the agent to 160° C for two hours is usually effective. The following are additional guidelines to help the worker decide the most appropriate means for decontamination. Any questions should be directed to the supervisor or EHRS. See tables in Appendix A for more information about decontaminants and their use in laboratories.

8.2 Chemical Decontamination

Chemical decontaminating agents can generally be split into two categories; chemical mixtures that are made to clean and disinfect surfaces and chemical mixtures that are made to do terminal disinfection of inanimate surfaces. Soap or detergent mixtures including disinfectants are made to clean dirty surfaces. These cleaners contain a soap or detergent to suspend gross contaminants into solution until they are rinsed off. A disinfectant is often added to help start the process of decontamination. Mixtures formulated to do terminal disinfection on inanimate surfaces contain no soap or detergents. These solutions are made to disinfect surfaces that are already clean. These agents would not necessarily be recommended for use on animals or human patients.

With few exceptions, any disinfecting chemical must be in contact with the surface for at least ten minutes for effective disinfection. Contact times of less than ten minutes often result in partial disinfection at best, and work only as a surface cleaner. Other variables that effect disinfection times are:

1. The amount or concentration of the contaminant.
2. The temperature (in general, colder temperatures require longer times than stated on the directions).
3. The type of agent to be decontaminated.
4. The dilution of the disinfectant.

Most disinfectants have directions that specify a dilution depending on the target agent to be disinfected and the type of surface to be disinfected. The directions for the disinfectant <u>must</u> be followed precisely for effective disinfection.

8.3 Autoclave Decontamination

Steam autoclaving may be used for decontamination, as long as:

1. The waste does not have volatile or reactive organics that could react with heat and steam,
2. the waste quantity does not exceed the capacity of the autoclave to decontaminate,
3. the waste con be contained in some way such that it will not grossly contaminate the interior of the autoclave, and
4. the waste is not radioactive.

Waste must be placed into an autoclavable bag and a secondary container must be used sufficient to contain the waste in the event the primary bag/container fails. The bag and the secondary container must be able to withstand temperatures from 250° F to 270° F. An autoclavable indicator (tape, etc.) that reacts to both duration and contact with steam and heat should be used to indicate effective decontamination.

It is suggested that autoclaves be dedicated to sterilization or decontamination, and not be used for both. If both decontamination and sterilization must be done with the same autoclave, then an empty cycle should be run between a decontamination cycle and a subsequent sterilization cycle to prevent residual cross contamination. Cycle times and temperatures are determined by the load size and the agent to be decontaminated. A quality control run should be done to assure complete decontamination is taking place before assuming the load is safe for disposal. Minimally, the autoclave should run at 121° C/250° F for 20 minutes. At least once a month a quality assurance run should be done to ensure that autoclaving is effective. Methods that only indicate an effective run after an appropriate contact time with heat and steam should be used, for example a biological indicator such as *B. stearothermophilius*.

8.4 Equipment Decontamination for Maintenance/Repairs

Building maintenance requests that can potentially expose maintenance personnel to biohazards must include a thorough description of the hazards that may exist. This includes work performed by outside contractors and in house personnel. Because of the large variety of tasks performed by maintenance personnel, a biosafety risk assessment must be performed on a case-by-case basis. If a directly responsible party is unavailable to assess risk, maintenance personnel should contact the area supervisor of EHRS. PPE for use by maintenance personnel for a give project should be selected based upon worst-case risk assessment because of the potential for unknown variables.

8.5 Procedures for Inactivation and Safety Containment of Toxins

Table 4 provides information about chemical inactivation of selected toxins. For complete inactivation of T-2 mycotoxin and brevetoxin, it is recommended that all liquid samples, accidental spills and non-burnable waste be soaked in a solution of 2.5% sodium hypochlorite (NaOCl) with 0.25 N NaOH for four hours. It is further recommended that cages and bedding from animals exposed to T-2 mycotoxin or brevetoxin be exposed to 0.25% NaOCl and 0.025 N NaOH for four hours. Exposure to 1.0% NaOCl for

thirty minutes is an effective procedure for laboratory solutions, equipment, animal cages, working areas and spills for inactivation of saxitoxin, tetrodotoxin, microcystin, palytoxin, ricin, botullinum toxin or staphylococcal enterotoxins (SEB). Increasing the concentration of disinfectant will not allow for shorter contact times.

Table 3

Inactivation of toxins by varying concentrations of NaOCl or NaOH (30 min. exposure)

Toxin	2.5% NaOCl + 0.25 N NaOH	2.5% NaOCl	1.0% NaOCl	0.1% NaOCl
Brevetoxin	Yes	Yes	No	No
Botulinum toxin	Yes	Yes	Yes	Yes
Microcystin	Yes	Yes	Yes	No
Palytoxin	Yes	Yes	Yes	Yes
Ricin	Yes	Yes	Yes	Yes
Saxitoxin	Yes	Yes	Yes	Yes
SEB	Yes?	Yes?	Yes?	Yes?
T-2 mycotoxin	Yes	No	No	No
Tetrodotoxin	Yes	Yes	Yes	No

Note: household bleach contains approximately 5.25% NaOCl.

All burnable waste from toxins should be incinerated at temperatures in excess of 1500° F. Autoclaving can be used for the protein toxins (ricin, botulinum toxin and SEB), but should not be used for any of the low molecular weight toxins. Table 5 provides information about heat/autoclave inactivation of selected toxins.

Table 4

Inactivation of toxins by autoclaving, or 10 min. exposure to varying temperatures of dry heat

		Dry Heat			
Toxin	Autoclaving	200°F	500°F	1000°F	1500°F
Brevetoxin	No	No	No	No	Yes
Botulinum toxin	No	No	No	No	No
Microcystin	No	No	Yes	Yes	Yes
Palytoxin	No	No	Yes	Yes	Yes
Ricin	Yes	Yes	Yes	Yes	Yes
Saxitoxin	No	No	Yes	Yes	Yes
SEB	Yes?	Yes?	Yes?	Yes?	Yes?
T-2 mycotoxin	No	No	No	No	Yes
Tetrodotoxin	No	No	Yes	Yes	Yes

Tap water with normal chlorination is <u>not</u> a useful medium for inactivation of any of these toxins. Stability at high and low pH varies with the toxin and is not a universal procedure for inactivation of toxin waste.

Procedures should be implemented to prevent contamination of personnel and equipment with these toxins. If the skin is accidentally exposed to toxins, it is recommended that it be washed immediately with soap and water. All procedures that may generate aerosols of toxins must be performed in a class III BSC. Except for botulinum toxin, the class III BSC can be in a BSL-2 laboratory. Aerosol exposures to botulinum toxin must be contained by a class III BSC in a BSL-3 laboratory.

IX. SELECT AGENTS AND TOXINS

The Public Health Security and Bioterrorism preparedness and Response Act of 2002 restricts the possession, use, handling, security and transfer of certain biological agents. The Act provides authority and responsibility to the CDC and USDA for regulating activities regarding select agents and toxins (SATs) in order to protect human and animal life. These two agencies have established separate as well as combined lists of agents that are subject to additional regulatory requirements. The lists of these agents may change according to the most recent information from the CDC or USDA. Users of biological materials are advised to monitor the CDC and USDA websites, or contact the campus Responsible Official for additional information or registration procedures.

9.1 OHSU Policy for Possession, Use and Transfer of Select Biological Agents and Toxins

SELECT BIOLOGICAL AGENTS AND TOXINS (SELECT AGENTS) No. 04-10-005

Effective Date: DRAFT 1/02/08

1. **Delegation to Vice President for Research**

The Vice President for Research shall establish policies, procedures, protocols and forms concerning the possession, use, and transfer of Select Agents and Toxins (SATs) on OHSU any controlled property, in compliance with the Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), the Animal and Plant Health Inspection Service (APHIS), and other applicable local, state and federal regulations. Such policies, procedures, protocols and forms shall provide for registration, security clearance, restrictions on access, biosafety, security and incident response, and such other measures deemed necessary or prudent to carry out the requirements of this section.

2. **Registration**

OHSU must register with and be certified by CDC, APHIS, and other regulatory agencies, as appropriate, if any individuals working in an OHSU controlled facility possess, use, or transfer SATs.

3. **Security Clearances and Restrictions on Access**

All individuals desiring access to SATs at an OHSU controlled facility must obtain a security clearance in advance from the Department of Justice through the RO. No such individual shall possess, use, or transfer SATs without prior written approval of the OHSU Responsible Official (RO). Individuals without a

security clearance may be granted access on a limited basis with the express permission of the RO, and must be accompanied and monitored at all times by a person who has received a security clearance.

4. **Security and Incident Response Plans**

Review and revision of the Security and Incident Response Plans are the responsibilities of the RO(s). The RO(s) shall consult with the Department of Public Safety (DPS) Director and the Emergency Management Administrator, and others, as appropriate, in developing and implementing Security and Incident Response Plans related to the possession, use, and transfer of SATs. The RO(s), DPS Director, Emergency Management Administrator, and/or the Vice President for Research shall review and revise the Security and Incident Response Plans annually and after any incident.

5. **Biosafety Plan**

Review and revision of the Biosafety Plan are the responsibilities of the RO(s). The RO(s) shall consult with the Institutional Biosafety Committee (IBC) and others, as appropriate, in developing and implementing a Biosafety Plan that is commensurate with the risks of the SATs located at OHSU controlled facilities. The RO(s), IBC, and/or Vice President for Research shall review the security plan annually and after any incident.

6. **Coverage**

Except as otherwise provided by law, this policy applies to all OHSU employees and others who possess, use, handle or transfer select agents at an OHSU controlled facility. The Vice President for Research may extend the policy to apply to persons in addition to those identified in applicable laws, but may not restrict the policy so as to exempt those identified by the law.

7. **Compliance**

A. The Director of the OHSU Research Integrity Office is responsible for enforcing this policy.

B. The RO(s) shall be advisory to the Director.

C. The RO(s) shall consult with the IBC, the Biosafety Officer(s), the Public Safety Director, the Emergency Management Administrator, the Information Security Officer, OHSU Legal Counsel and others, as appropriate, in responding to technical issues and implementation of this policy.

D. A person aggrieved by a decision of the Director of the OHSU Research Integrity Office may appeal that decision to the Vice President for Research within ten (10) working days of the Director's decision. The decision of the Vice President for Research shall be final. The University's general Grievance Procedure (Policy No. 03-50-001) shall not apply to any decision made under this policy.

Background:

- **42 CFR 73**
- **7 CFR 331**

- **9 CFR 121**
- **USA Patriot Act (18 USC 175b)**

Implementation date: June 3, 2003

Related policies, procedures and forms:

- **Policy No. 04-06-001, Research Involving Recombinant DNA**
- **Policy No. 04-10-010, Select Agents and Toxins: Responsibilities and Authority of the Responsible Official**

Responsible office: Research Integrity Office

9.2 Select Agent Program Components

OHSU must register with and be certified by CDC or APHIS if any individuals working in an OHSU facility possess, sue or transfer SATs. Such individuals are required to provide to OHSU's RO the following information upon request:

1. Names of all individuals with access to SATs,
2. Identifying information about the SATs,
3. Locations of the SATs (building, room and floor plan),
4. General research objectives related to the SATs, and
5. Any additional information requested by the RO that is necessary to fulfill CDC or APHIS regulations.

Possession, use or transfer of SATs require prior written approval from the RO. Any change in the information provided in A through D above requires an application to the CDC or APHIS through the RO before the change may occur. At the conclusion of a project, final destruction or transfer of SATs also requires prior approval from the RO, CDC or APHIS.

All individuals with access to SATs at an OHSU facility must obtain a security clearance from the Department of Justice through the RO. The RO will perform, or direct to be performed, criminal, immigration, national security and other electronic database reviews in performing the security clearance. Access could be denied to individuals who:

1. Are "restricted persons" under the USA Patriot Act (18USC175b); or
2. Are reasonably suspected by law enforcement or intelligence agencies of engaging in domestic or international terrorism.
3. Have been convicted of a felony or been committed to a psychiatric facility.

Every person who has access to SATs at OHSU must either have security clearance from the RO or must be accompanied and monitored by such a person. This includes visitors, students, guests and employees performing routine cleaning, maintenance and repairs. In addition, every person entering and leaving such a site must sign in and out on the logbook located near the secured area.

The RO will implement and monitor a safety and emergency response plan related to the possession, use and transfer of SATs. The RO will consult with the IBC and the Security Director in carrying out this duty. The emergency plan must address naturally occurring emergencies, such as fire, earthquake, power outages, hurricanes, as well as human-caused emergencies such as protests, vandalism, terrorist action, etc.

The RO will implement and maintain biosafety, incident response and security plans that are commensurate with the risks of the SATs located at OHSU facilities. All plans will undergo annual review and a review after any incident and will include, but not be limited to:

1. Physical security, including physical separation of areas in which SATs are located;
2. Electronic security;
3. Training for all employees, guests and visitors, including systems to verify understanding;
4. Educational and experience criteria for employees;
5. Reporting requirements for a variety of problem situations;
6. Protocols for internal lab-to-lab transfers of SATs;
7. Inspection of packages on entrance/exit of security/select agent areas;
8. Inventory control of SATs;
9. Documentation of each person's entry into and exit from select agent areas;
10. Provisions for routine cleaning, maintenance and repairs; and
11. Provisions for reporting suspicious person and activities.

All transfers of SATs from one area to another area must have prior approval from the RO, be documented after the fact and follow appropriate packing and transportation requirements.

All transfers from one facility to another, including between OHSU campuses, must have prior approval from the RO, and CDC or APHIS, must be documented after the fact and follow the applicable packing and transportation requirements.

Notifications. The RO is advisory to the Director of the OHSU Research Integrity Office who will enforce this policy. The RO will consult with the IBC, the BSO(s), the Public Safety Director, the Information Security Officer, the Legal Department and others in responding to technical issues and implementing this policy. An OHSU affiliated individual who disagrees with the decision of the Director of the OHSU Research Integrity Office may appeal that decision to the Vice President for Research with 10 working days. The decision of the Vice President for Research will be final.

PIs may apply for registration for possession of SATs by following the steps outlined below:

1. Contact the RO for the campus. The RO is listed on the EHRS website http://ozone.ohsu.edu/ and the IBC website: http://www.ohsu.edu/ra/ibc.
2. Assist the RO by providing information necessary to complete the registration forms,
3. Review and comply with the OHSU policy regarding select agent possession, transfer and use,
4. Provide information to complete security risk assessments,
5. Ensure employees with access to the area attend training,
6. Ensure proper inventory tracking and security measures are being followed,
7. Contact the RO immediately in the event of loss or theft of the agent.

X. EMPLOYEE TRAINING

10.1 Personnel Working in Animal Facilities

Personnel Working in Animal Facilities. All personnel who work in animal facilities at OHSU must attend training on animal biosafety This training is also require for anyone who may come in contact with animals, share airspace with animals, or enter necropsy areas unescorted. Supervisors and animal care staff should ensure training has been completed prior to an employee being permitted access to animals.

Personnel Working with Animal and/or Human Tissues or Body Fluids. All personnel who work with, handle or transport animal tissues or body fluids must attend training on animal biosafety. Those handling human tissues or fluids must have Bloodborne pathogen training and be offered the HBV vaccination. Human Bloodborne pathogen training must be completed on an annual basis. Those shipping biological material need training specific to the category of hazard associated with the material. This training must be completed at least every 23 months. Supervisors and their designees will ensure that training has been completed before work with animal/human tissue or animal/human body fluids.

10.2 Training Records

Training records shall be maintained for at least 3 years from the date on which the training occurred and are to include the following information:

1. The date(s) of the training,
2. An outline of the training completed,
3. The names and person(s) conducting the training sessions, and
4. The names of the person(s) attending the training.

XI. REFERENCES

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APPENDIX A

DECONTAMINANTS AND THEIR USE IN LABORATORIES

The following tables provide information regarding the effectiveness, characteristics and applications of decontaminants available for use in laboratories. These tables should be used to determine the most appropriate product/system for the specific agent in use and the type of work being performed.

	Use Parameters				Effective Against					Important Characteristics						
Decontaminant	Conc. of Active Ingredient	Temperature (°C)	Relative Humidity (%)	Contact Time (Min)	Vegetative Bacteria	Lipid Viruses	Tubercle Bacilli	Hydrophilic Viruses	Bacterial Spores	Inactivated by Organic Matter	Residual	Corrosive	Skin Irritant	Eye Irritant	Respiratory Irritant	Toxic (absorbed through skin)
Autoclave (15 lb/in^2)	Saturated steam	121		50-90	+	+	+	+	+							
Autoclave (27 lb/in^2)	Saturated steam	132		10-20	+	+	+	+	+							
Dry heat oven	N/A	160-180		180-240	+	+	+	+	+							
Incinerator	N/A	649-926		1-60+	+	+	+	+	+							
UV radiation (253.7 µm)*	40 µW/cm^2			10-30	+	+	+	±		+						
Ethylene oxide	400-800 mg/l	35-60	30-60	105-240	+	+	+	+	+		+				+	+
Paraformaldehyde (gas)	0.3 g/ft^3	>23	>60	60-180	+	+	+	+	+		+				+	+
Quaternary ammonium	0.1-2%			10-30	+	+				+						+
Phenolic compounds	0.2-3%			10-30	+	+	+	±		±	+	+	+	+	±	+
Chlorine compounds	0.01-5%			10-30	+	+	+	+	±	+	±	+	+	+	+	+
Iodophor compounds	0.47%			10-30	+	+	+	±		+	+	+	+	+		+
Alcohol (ethyl, isopropyl)	70-85%			10-30	+	+		±						+		+
Formaldehyde (liquid)	7-8%			10-30	+	+	+	+	±		+		+	+	±	+
Glutaraldehyde	2%			10-600	+	+	+	+	+		+		+	+	+	+

+ very positive response; ± less positive response. Blank denotes negative response/not applicable.

* Soil and other materials are not penetrated by UV radiation.

	Use Parameters				Applications										
Decontaminant	Conc. of Active Ingredient	Temperature (°C)	Relative Humidity (%)	Contact Time (Min)	Work Surface Maintenance	Floor Maintenance	BiOhzard spill, floor surface	Biosafety Cabinet Maintenance	Biosafety Cabinet Spill	Biosafety Cabinet Decon.	Room/air system Decon.	Water Bath	Liquid Waste	Infectious Waste	Contaminated Glassware
Autoclave (15 lb/in^2)	Saturated steam	121		50-90									+	+	+
Autoclave (27 lb/in^2)	Saturated steam	132		10-20									+	+	+
Dry heat oven	N/A	160-180		180-240											+
Incinerator	N/A	649-926		1-60+										+	
UV radiation (253.7 µm)*	40 µW/cm^2			10-30				±							
Ethylene oxide	400-800 mg/l	35-60	30-60	105-240											±
Paraformaldehyde (gas)	0.3 g/ft^3	>23	>60	60-180						+	+				
Quaternary ammonium	0.1-2%			10-30	+	+		+				±			+
Phenolic compounds	0.2-3%			10-30	+	+	±	+	±			+			+
Chlorine compounds	0.01-5%			10-30			+		+			±	+		+
Iodophor compounds	0.47%			10-30	+	+	±	+	±			±			+
Alcohol (ethyl, isopropyl)	70-85%			10-30	+			+							
Formaldehyde (liquid)*	7-8%			10-30			±						±		±
Glutaraldehyde	2%			10-600											+

+ very positive response; ± less positive response. Blank denotes negative response/not applicable.
* The pungent and irritating characteristics of formaldehyde preclude its use for biohazard spills.

	Use Parameters				Applications										
Decontaminant	Conc. of Active Ingredient	Temperature (°C)	Relative Humidity (%)	Contact Time (Min)	Contaminated Instruments	Equipment Surfaces	Equipment total Decon.	Floor Drain	Animal Injection Site	Contaminated Bedding	Infected Animal Carcass	Microbial Transfer Loop	Books, Paper, Shoes	Electrical Instruments	Lensed Instruments
Autoclave (15 lb/in^2)	Saturated steam	121		50-90	+					+	±				
Autoclave (27 lb/in^2)	Saturated steam	132		10-20	+					+	±				
Dry heat oven	N/A	160-180		180-240	+					±					
Incinerator	N/A	649-926		1-60+						+	+	+			
Ethylene oxide	400-800 mg/l	35-60	30-60	105-240	±		±					+	+		
Paraformaldehyde (gas)	0.3 g/ft^3	>23	>60	60-180			+							+	
Quaternary ammonium	0.1-2%			10-30		+									
Phenolic compounds	0.2-3%			10-30		+		+							
Chlorine compounds	0.01-5%			10-30	+	+		+							
Iodophor compounds	0.47%			10-30		+									
Alcohol (ethyl, isopropyl)	70-85%			10-30		+			+						
Formaldehyde (liquid)	7-8%			10-30	±	±									
Glutaraldehyde	2%			10-600	+	±									±

+ very positive response; ± less positive response. Blank denotes negative response/not applicable.