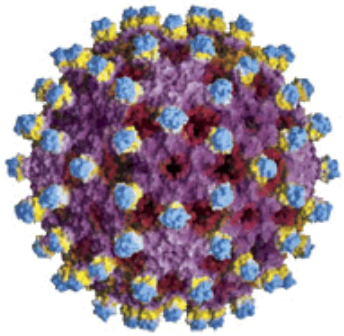
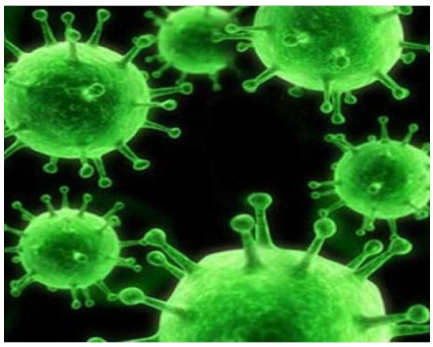
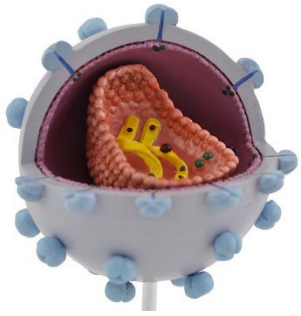
EXPOSURE CONTROL PLAN



Revision 08.2023

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Contents

Exposure Control Plan Approved By:

DocuSigned by:
Erin Rothwell
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8/1/2023

Signature Date

Erin Rothwell, Ph.D., Vice President for Research

DocuSigned by:
Caren Frost
DE613FE33E0345E...

8/1/2023

Signature Date

Caren J. Frost, Ph.D., M.P.H., Associate Vice President for Research Integrity & Compliance

DocuSigned by:
Neil Bowles
376CBF2FCE9F4ED...

8/1/2023

Signature Date

Neil E. Bowles, Ph.D., Biosafety Officer

DocuSigned by:
Fred Monette
FDE39FA28FB4426...

8/1/2023

Signature Date

Fred Monette, M.S., Executive Director, Environmental Health and Safety

Policy

A. Purpose

The University of Utah is committed to reducing the risks to individuals who may be exposed to Bloodborne Pathogens and has developed this Bloodborne Pathogen Exposure Control Plan to meet the requirements of the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standard (codified in 29 CFR 1910.1030) and to address concern for personal safety.

The Bloodborne Pathogen Standard requires that specific safety issues be addressed in the Exposure Control Plan including the following topics:

- Methods of compliance (e.g., engineering controls, work practices, decontamination procedures, and personal protective equipment used to minimize exposures);
- Faculty/employee/student post-exposure procedures;
- Communication of hazards to faculty/employees/students;
- Procedures for hepatitis B vaccinations, post-exposure vaccinations, and follow- up; and
- Recordkeeping practices.

The specific methods instituted to implement each of these topics are described in the sections below. The Exposure Control Plan will be reviewed and updated annually by the University of Utah Biosafety Officer to reflect new or modified tasks or procedures that affect potential occupational exposure situations, as well as changes in the Federal Guidelines.

While this document serves as the Campus-wide Exposure Control Plan (ECP) for the University Of Utah, the Office of Environmental Health and Safety (EHS) has developed ECP templates that can be adapted and customized for individual laboratories or other settings or facilities, which can be found here or by contacting the Biosafety Office (Biosafety@ehs.Utah.edu). These should identify risks, work and engineering controls, PPE requirements and waste disposal procedures specific to the facility or workplace environment. Principal Investigators and Supervisors of all research laboratories and facilities that work with human blood and/or other potentially infectious material, or where there is the potential for an occupational exposure, must provide staff access to the University of Utah ECP. In addition, they must develop a specific ECP for their facility that is reviewed by all staff at the time of work assignment, whenever changes are made and annually thereafter.

B. Scope

This written program applies to all University of Utah research and academic activities performed on the Academic Campus, at the University Hospital and School of Medicine, the Huntsman Cancer Institute, or at off-campus facilities where there is the potential for exposure to bloodborne pathogens, blood or other potentially infectious material (OPIM). Students are covered as well as part- and full-time employees. The University of Utah Health Care System has developed their own Bloodborne Pathogen Exposure Control plan that applies to all Hospital and Clinic employees who are at risk of an occupational exposure to blood or OPIM, which can be accessed through Pulse.

C. Roles and Responsibilities

1. Office of Environmental Health and Safety (EHS):

The responsibilities of EHS include, but may not be limited to, the following:

a. Designate the Biological Safety Officer (BSO) as the individual to oversee the University of Utah Exposure Control Plan.
b. Develop, implement, evaluate and periodically update the Exposure Control Plan for the University.
c. Assist departments with hazard assessments to determine jobs or tasks where exposure to blood or OPIM is possible.
d. Promote practices, procedures, and methods that conform to the concept of universal precautions.
e. Ensure that employees/students with potential exposure to bloodborne pathogens observe universal precautions.
f. Determine, in conjunction with the affected investigator/department, applicable engineering controls, safe work practices, housekeeping methods, and personal protective equipment (PPE) to prevent blood and/or OPIM exposure to campus community members.
g. Provide consultation and technical information on the safe handling of blood or OPIM.
h. Provide guidance and technical assistance to laboratories engaged in HIV, HBV, and HCV research.
i. Assist departments in the identification of employees/students that have potential exposures to bloodborne pathogens.
j. Provide direction on approved medical facilities capable of providing the confidential

post exposure evaluation and follow-up.

k. Create training opportunities as deemed necessary and appropriate for each affected department.

l. Ensure that individual investigators are compiling and maintaining (for a minimum of three years) all training records relative to the Exposure Control Plan. Records are also maintained by EHS.

m. Coordinate the proper management and disposal of regulated waste; appropriate disposal bags and containers can be obtained from EHS through the Safety Administrative Management (SAM) system or can be procured by each department/facility/laboratory.

n. Assist departments in communicating the Exposure Control Plan to third-party vendors who perform tasks on campus that potentially implicate exposure control issues, upon request.

o. Assist investigators/departments with Bloodborne Pathogens and exposure control issues, upon request.

p. Conduct periodic inspections of University of Utah facilities to ensure compliance with the Exposure Control Plan.

q. Review and recommend purchases of biological safety cabinets and other related safety equipment.

r. Advise in the disinfection of facilities and equipment.

s. Assist in the development of laboratory/facility-specific safety and exposure control plans and training programs.

t. Serve as university liaison to regulatory authorities.

u. Provide a means for suggestions, complaints, and concerns regarding the Exposure Control Plan. These can be sent directly to the Biosafety office: EHS can be contacted by telephone at 801-581-6590 or by e mail at biosafety@ehs.utah.edu, or can be submitted using the online Hazard/Near Miss Report Form.

2. Principal Investigators and/or Supervisors:

Supervisors (including Principal Investigators) have a key role in the successful development, implementation and monitoring of the University of Utah Exposure Control Plan. Supervisors support and respect each employee's right to a safe working environment. The responsibilities of each supervisor include, but may not be limited to, the following:

a. Ensure full compliance with the OSHA Bloodborne pathogen standard in the facility under their direction, as well as to other local, state and federal regulations that apply to

their work environment, including the Exposure Control Plan.

b. Principal Investigators of research laboratories must register their work with the Institutional Biosafety Committee (IBC) providing copies of training documentation and laboratory-specific ECPs or Biosafety Manuals. Registration for laboratory-based research is conducted using an online system, BioRAFT. However, investigators conducting research involving the introduction of recombinant nucleic acid molecules or biohazards into human subjects will need to register their work with the IBC through ERICA, a web-based platform used by the University to ensure compliance with Human Subject Research Participant Protection regulations.

c. Clearly identify the use of blood, products made from human blood, plasma, products made from plasma, human or non-human primate cell lines or OPIM when registering or amending a protocol with the IBC.

d. Conduct a risk assessment to identify potentially hazardous procedures involving blood or OPIM, develop facility-specific Exposure Control Plans/Biosafety Manuals, develop Standard Operating Procedures (SOPs), instruct and train all personnel and students working in the lab on safe work practices, keep the lab space clean and up-to-date, and follow regulations for disposal of infectious waste. The IBC has produced a Fact Sheet on how to develop and write SOPs and has developed examples of SOPs that can be adapted for use in labs working with blood or OPIM (**Appendices G-J**).

e. Provide all personnel with a potential exposure to blood or OPIM (at the time of job assignment) access to this document and the facility-specific Exposure Control Plan, which must be updated (as necessary) and reviewed at least annually.

f. Ensure all affected personnel undertake initial (at the time of job assignment) and annual refresher bloodborne pathogen training. EHS provides training through Bridge: information on training requirements can be found here and links to training sessions can be found here. Compile and retain employee/student training records for a minimum of three years: attach all training records to the BioRAFT or ERICA registration.

g. Ensure that universal precautions are understood and executed by employees/students with possible exposure to bloodborne pathogens.

h. Promote practices, procedures, and methods that conform to the concept of universal precautions.

i. Design and implement engineering controls and institute work-practice control procedures that will eliminate or minimize potential exposure to blood and OPIM.

j. Provide appropriate PPE to employees/students that have potential exposure to bloodborne pathogens. Reusable PPE must be laundered at no cost to the employee, using an approved laundry facility.

k. Ensure that employees wear PPE at all times when in the laboratory and remove PPE when leaving the lab.
l. Maintain a clean and sanitary workplace environment.
m. Post Laboratory Hazard Caution Signs, identifying the type of work that is occurring in the lab. Work with human blood or OPIM must be performed using Biosafety Level 2 (BSL-2) practices: human samples obtained from patients with a known infectious disease may require additional containment and practices.
n. Develop and implement cleaning schedules as deemed appropriate for the types of activities and facilities involved.
o. Comply with additional criteria established for HIV, HBV, and HCV laboratories.
p. Make confidential medical evaluation and follow-up immediately available to an exposed individual, following an exposure incident.
q. Report exposure incidents to the Biological Safety Officer.
r. Encourage employees to report any changes in their health status.
s. Maintain needlestick logs (**Appendix C**) and provide copies to EHS upon request.
t. Perform an annual Safer Sharps Alternative Review (**Appendix D**).
u. Coordinate facility-specific training required by the Exposure Control Plan.
v. Affix appropriate labels to containers of regulated waste, refrigerators, freezers, and other equipment containing blood or OPIM, and other containers of blood or potentially infectious materials.
w. Post the universal biohazard symbol and appropriate Biological Safety Level (BSL) at the entrance of research laboratories. The facility BSL is set by the IBC.
x. Ensure waste is labeled and disposed of properly.
y. Provide, at no cost to the employee, all supplies, PPE, and controls that are necessary for compliance with the Exposure Control Plan. Vaccinations, including those for Hepatitis B virus and any determined necessary by the IBC, will be provided at no cost by the University of Utah.
z. Conduct periodic surveillance of activities within their respective areas to ensure compliance with the Exposure Control Plan.
aa. Comply with shipping requirements for blood or OPIM.

3. Employees and Students:

All employees and students have a basic right to a workplace that is free of recognized hazards that may cause injury or illness. With respect to bloodborne pathogens, individuals have the right to information and training for controlling exposures to bloodborne pathogens, the availability of vaccination for hepatitis B, and post-exposure medical care and post-exposure consultation.

Responsibilities of employees and students include, but may not be limited to, the following:

a. Read, understand, and comply with the requirements of the University of Utah and facility-specific Exposure Control Plans.
b. Adhere to the established policies, Standard Operating Procedures (SOPs) and guidelines for biological safety, as trained, and following the supervisor's instructions.
c. Notify supervisor and EHS if job tasks and responsibilities present occupational exposure concerns that have not been previously identified.
d. Alert others in the work area, before work begins, of activities that may expose themselves or others to bloodborne pathogens or OPIM.
e. Follow universal precautions when handling blood or OPIM.
f. Follow established work practice controls to eliminate or minimize occupational exposure.
g. Be aware of engineering controls in the work place and the proper use of those controls.
h. Be aware of the proper use, limitations, and location of PPE.
i. Use appropriate work practice and engineering controls and PPE to eliminate or minimize exposure. Wear PPE at all times when in the laboratory and remove PPE when leaving the lab.
j. Be aware of and observe established housekeeping procedures (e.g., use mechanical devices to clean up broken glass and not bare hands).
k. Maintain work area in a clean and sanitary manner.
l. Understand the additional requirements and protection for personnel working with HIV, HBV, or HCV, and follow established procedures.
m. Attend initial or refresher biosafety and bloodborne pathogens training. EHS provides training through Bridge: information on training requirements can be found here and links to training sessions can be found here.
n. After receiving initial EHS BBP training, you must register in the Hepatitis B virus vaccination program in Open Range, administered by Occupational Medicine. If you have not previously registered in the system (and have a paper record of vaccination status), during annual training you will receive information on how to register in Open Range and how to obtain vaccination, an antibody titer, or decline vaccination.
    i. If you have previously declined vaccination but change your mind, contact EHS (Biosafety@EHS.Utah.edu) and Occupational Medicine (occupational.health@hsc.utah.edu). Do not wait for the next training session
o. Immediately report all exposure incidents to your supervisor and EHS using the online

Hazard/Near Miss Report Form.

p. Inform your immediate supervisor of any unsafe practices or conditions in the work area. Reports of unsafe practices can also be reported to EHS (https://oehs.utah.edu/resource-center/forms/hazard-report). Concerns over research misconduct or misbehavior can be reported anonymously at www.ethicspoint.com.

q. Report any change in health status to your supervisor if there is a possibility it may be work related.

r. Make certain that labels are appropriately affixed. Ensure waste is labeled with the words "Biohazardous Waste" and the universal biohazard symbol; dispose of waste properly.

s. Notify supervisor to report labeling problems.

t. Comply with all applicable requirements established in the OSHA Bloodborne Pathogens Standard and this Exposure Control Plan.

4. Institutional Biosafety Committee (IBC):

The IBC is authorized by the Vice President for Research to formulate policy and procedures related to the use of biohazardous agents, including: human pathogens, oncogenic viruses, other infectious agents, human gene transfer, and recombinant or synthetic nucleic acid molecules (rsNA), as well as samples that may harbor pathogenic organisms, such as human blood or OPIM, and acute biological toxins.

Laboratory-based research involving samples collected from human subjects, investigators can register their work with the IBC through BioRAFT or through ERICA, a web-based platform used by the University to ensure compliance with Human Subject Research Participant Protection regulations. As part of the registration process the PI/supervisor must submit copies of training documentation and laboratory-specific ECPs or Biosafety Manuals.

The IBC will:

a. For work with blood or OPIM not known to harbor infectious agents, conduct an administrative review by the IBC Chair, Vice Chair, Director and /or Administrator. Approval at BSL-2 will be granted for up to 5 years.

b. For work with blood or tissue known to harbor infectious agents, or work with the pathogenic organism themselves (such as HBV, HCV, HIV or SARS-CoV-2), conduct a full review by the convened IBC. Approval will be granted for up to 3 years.

c. Set containment levels in accordance with NIH and Centers for Disease Control and Prevention (CDC) guidelines, and adopts emergency plans and procedures covering accidental spills and personnel contamination.

d. Determine the necessity for health surveillance and prophylaxis for research projects.

5. Occupational Medicine

The University of Utah Health Occupational Medicine Clinics offer services that treat work related injuries as well as preventive work physicals. In relation to the Bloodborne Pathogens standard, Occupational Medicine offers Hepatitis B virus vaccination at their RedMed Clinic. The Hepatitis B virus vaccination program uses a system based in Open Range to track vaccinations, titer checks and vaccination declinations.

Occupational Medicine will make vaccination records available upon request: requests may be emailed to occupational.health@hsc.utah.edu.

6. College Safety Committees and Reporting

All colleges must establish, support, and maintain active safety committees. Detailed requirements for Safety Committees and their Roles and Responsibilities can be found here.

The primary functions and responsibilities of college safety committees are to:

a. Assist the Dean/Director in fulfilling college/department-level health and safety responsibilities.

b. Provide peer-to-peer safety consultation and review of existing or proposed operations withrespect to health and safety and compliance with University policies.

c. Serve as the primary point-of-contact/liaison with Environmental Health and Safety to facilitate implementation of campus-wide health and safety requirements at the college/department level.

d. Serve as primary contact for campus Emergency Management.

e. Meet routinely, e.g., quarterly or monthly.

f. Provide a local mechanism for faculty, staff, and students to raise health and safety issues and concerns.

Procedures

A. Introduction

This Exposure Control Plan was developed to protect against potential exposures to bloodborne pathogens. According to OSHA, bloodborne pathogens are microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and Human Immunodeficiency Virus (HIV). Provided below is a brief overview of each of these viruses:

- Hepatitis B viral infection is caused by HBV, and was formerly known as "serum hepatitis." Of all bloodborne diseases, HBV poses the greatest risk for infection among health care providers and laboratory researchers because it can be easily transmitted through needlesticks and other types of percutaneous exposures. The virus causes inflammation of the liver and can lead to serious and occasionally fatal disease. Following an exposure an unvaccinated person should be offered treatment with HB immune globulin and HBV vaccination. An effective vaccine is available and must be offered to personnel who may be exposed. Visit the Centers for Disease Control and Prevention (CDC) website for more information.

- Hepatitis C viral infection is caused by Hepatitis C Virus (HCV). HCV poses a risk for infection among health care providers and laboratory researchers because it is transmitted through needlesticks and other types of percutaneous exposures. Similar to HBV, the virus causes inflammation of the liver and can lead to serious and occasionally fatal disease. Post exposure diagnostic testing should be completed, but at the present time post exposure prophylaxis (PEP) is not recommended for personnel who have occupational exposure to blood and other body fluids. Due to increases in injection drug use over the past 10 years the incidence of HCV has increased dramatically. Visit the CDC website for more information.

- Acquired Immunodeficiency Syndrome (AIDS) is a disease caused by HIV. HIV is a retrovirus which suppresses the immune system leaving the infected individual vulnerable to opportunistic infections and cancers. These infections become increasingly severe and eventually lead to death. No cure for HIV has been found. Following occupational exposure, immediate (starting within 72 hours) post-exposure prophylaxis with 3 or more antiretroviral drugs for a 4-week duration is

recommended. PEP is highly effective at preventing HIV infection. Visit the CDC website for more information.

In addition to HIV, HBV, and HCV, there are other viruses, bacteria, and parasites that may be present in blood, human body fluids, or tissues. A few of these agents include:

Disease	Causative Agent
Babesiosis	*Babesia microti*
Brucellosis	*Brucella* species
COVID-19	SARS-CoV-2
Creutzfeldt-Jakob Disease (CJD)	Prion
Leptospirosis	*Leptospira interrogans*
Malaria	*Plasmodium* species
Relapsing Fever	*Borrelia duttoni, Borrelia hermsii, Borrelia parkerii, Borrelia recurrentis*
SIV Infection	Simian Immunodeficiency Virus
Syphilis	*Treponema pallidum*
T-cell Leukemia	Human T-lymphotropic virus Type 1
Viral Encephalitis	Arboviruses
Viral Hemorrhagic Fevers	Ebola, Marburg, Lassa fever viruses
Viral Meningitis	Arenaviruses (e.g., Lymphocytic Choriomeningitis Virus)

Note: The bacterial and parasitic diseases listed above are treatable with antibiotics or other therapy. There are no specific, effective treatments for the viral diseases but may be preventable by vaccination.

Bloodborne pathogens may also be present in the following sources of potentially infectious materials of human origin:

- Amniotic fluid
- Body fluids visibly contaminated with blood (or unknown body fluids)
- Cerebrospinal fluid (CSF)
- Pericardial fluids
- Peritoneal fluids

- Pleural fluid
- Saliva in dental procedures
- Semen
- Synovial fluid
- Vaginal secretions

It is estimated that approximately 2% of US residents are infected with a bloodborne pathogen, based on the prevalence reported for HIV, HBV, and HCV by the CDC. Rates may be significantly different in samples from other countries.

Certain infectious materials handled by university personnel are also regulated under the OSHA Bloodborne Pathogens Standard. These materials should be handled in the same manner as human blood or body fluids:

- Animals that have been experimentally infected with HIV, HBV or other bloodborne pathogens.
- Blood and tissues from experimental animals infected with HIV, HBV or other bloodborne pathogens.
- Cell lines or tissue cultures containing HIV, HBV or HCV.
- Culture media or other solutions which contain HIV, HBV or HCV.
- Primary human and non-human primate cell and tissue cultures, including established cell lines. In 1994, OSHA issued an interpretation clarifying the applicability of the Bloodborne Pathogen Standard to human cell lines (for example, HeLa or HEK293). According to the interpretation, human cell lines are considered to be potentially infectious and within the scope of the BBP Standard unless the specific cell line has been characterized to be free of hepatitis viruses, HIV, Epstein-Barr virus, papilloma viruses and other recognized bloodborne pathogens. However, as it is impossible for cell lines to be tested for all adventitious agents, the University of Utah Policy is that all human and non-human primate cell lines must be handled according to the BBP Standard and at Biosafety Level 2, or higher.
    - Although ATCC tests cell lines for common pathogens and ships some at BSL-1, they state that "It is not feasible to test every cell line for the presence of every possible adventitious agent. It is strongly recommended that all human and other primate cell lines be handled at the same biosafety level as a cell line known to carry HIV or hepatitis virus."
    - Based on these requirements, the IBC and Office of Comparative Medicine have established policies for the injection of human cells and tissues into animals (see **Appendix K**).

Bloodborne pathogens may be transmitted if human blood or OPIM comes in contact with your blood or body fluids. Exposures often occur through needlesticks, direct contact of materials on non-intact skin, or splashes to the eyes, mouth, and nose.

Individuals that may have a reasonable chance of encountering human blood, body fluids, or OPIM while performing their normal job duties are covered by the OSHA Bloodborne Pathogens Standard.

B. Overview

The University of Utah Exposure Control Plan is designed to allow for timely and accurate identification, evaluation (including exposure), control and monitoring of bloodborne hazards in the laboratory environment and within other facilities/areas of the University. This document forms the basis for effective management of biological hazards in general, and more specifically, pathogens known to be carried in blood or OPIM as defined by the OSHA Bloodborne Pathogen Standard.

The University of Utah President is the chief administrative officer for the campus and holds ultimate responsibility for implementation of the Exposure Control Plan at all facilities under campus control. The EHS Biosafety Office is responsible for monitoring compliance with the Exposure Control Plan.

The Biological Safety Officer (BSO) works closely with campus administrators to develop any additional policies and practices needed to support the effective implementation of the Exposure Control Plan, as well as review, revise, or update the Exposure Control Plan as needed. In a coordinated effort with campus administration (e.g., Deans, Directors, Chairs, Supervisors), hazards will be identified, individuals will be trained and vaccinated when needed, and records will be kept to qualify the individuals for periodic retraining.

Individual departments and units are responsible for ensuring that the provisions of the University of Utah Exposure Control Plan and the mandates of the OSHA Bloodborne Pathogens Standard are carried out. Departments and units which have been identified as potentially having personnel with potential exposure to blood or OPIM include, but are not necessarily limited to:

- Athletics
- Center for Comparative Medicine
- College of Engineering
- College of Medicine

- College of Nursing
- College of Pharmacy
- College of Science
- Custodial Services
- Department of Anesthesiology
- Department of Biochemistry
- Department of Biology
- Department of Bioengineering
- Department of Chemical Engineering
- Department of Chemistry
- Department of Dental Engineering
- Department of Dermatology
- Department of Exercise and Sports Medicine
- Department of Family and Preventive Medicine
- Department of Health, Kinesiology and Recreation
- Department of Health Promotion and Education
- Department of Human Genetics
- Department of Internal Medicine
- Department of Materials Science and Engineering
- Department of Mechanical Engineering
- Department of Medical Laboratory Sciences
- Department of Medicinal Chemistry
- Department of Neurobiology and Anatomy
- Department of Neurology
- Department of Neurosurgery
- Department of Nursing
- Department of Nutrition and Integrative Physiology
- Department of Obstetrics and Gynecology
- Department of Occupational Therapy
- Department of Oncological Sciences
- Department of Ophthalmology
- Department of Orthopedics
- Department of Pathology
- Department of Pediatrics
- Department of Pharmaceutics and Pharmaceutical Chemistry
- Department of Pharmacology and Toxicology
- Department of Pharmacotherapy
- Department of Physical Medicine and Rehabilitation
- Department of Physical Therapy
- Department of Physiology

- Department of Radiation Oncology
- Department of Radiology
- Department of Surgery
- Facility Operations
- Housing and Residential Education
- Lassonde Entrepreneur Institute
- Utah Museum of Natural History
- Olpin Union
- Environmental Health and Safety (EHS)
- Public Safety Department
- School of Biological Sciences
- School of Medicine
- School of Dentistry
- Student Life Center
- University Student Apartments

Some of the job tasks or procedures performed by individuals that present potential exposures to bloodborne pathogens include, but are not necessarily limited to the following:

- Handling human blood, components, or products.
- Handling human-derived materials that may be contaminated with blood.
- Handling unfixed human organs or tissues.
- Culturing primary human cells or cultures known to contain HIV, HBV, HCV, or other bloodborne pathogen.
- Culturing established human cell lines.
- Handling OPIM (e.g., semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, unfixed human tissue or organs, animals and tissues of animals known to be infected with HIV, HBV, or other bloodborne pathogen, and all other body fluids in situations where it is difficult or impossible to differentiate between body fluids).
- Cleaning up spills of blood or body fluids from unknown sources. For some jobs and activities, such as custodians, athletic trainers, housing staff, etc., the most likely exposure to blood or OPIM will arise from cleaning spilled blood or body fluids. Clean up procedures specific to these activities are described in **Appendix A.**

C. Universal Precautions

Universal Precautions assumes that **all** blood, body fluids (e.g., semen, vaginal secretions,

cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, and saliva in dental procedures), tissues, and OPIM are infectious for HIV, HBV, HCV, and other bloodborne diseases. Because no test method can offer complete assurance for the absence of all bloodborne pathogens, Universal Precautions must always be observed when handling blood and OPIM collected from any source.

Universal precautions must be observed by all university personnel to prevent contact with blood and OPIM. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids will be considered potentially infectious.

The only exception to the use of universal precautions is in rare instances, such as unexpected medical emergencies, where employees may not be able to put on appropriate PPE. In those situations, where judgment must be afforded by the provider of health care or public safety services, the employees must not ignore the underlying concept of universal precautions nor should he or she decline to use PPE simply because it is not practical to use. Only under unexpected, extraordinary circumstances will employees have the option to not use PPE. An example would be if they feel such equipment would prevent the proper delivery of health care or public safety services or would create a greater hazard to their personal safety if they used such equipment. The exemption provided in the standard does not apply to the general concept of universal precautions, but only to the use of PPE under rare and relatively limited circumstances.

D. Exposure Determination

University of Utah has performed an exposure determination to identify which employees, students, and visitors may be more likely at risk of exposure to bloodborne pathogens. This determination was made without regard to the use of PPE and regardless of the frequency of exposure. However, job assignments will ultimately determine which individuals may be exposed to bloodborne pathogens and this must be determined by the employee's Department/Supervisor/Principal Investigator. In addition, as previously noted, employees of University of Utah Health (UHealth) must abide by the provisions of the ECP of that entity rather than this document.

It is difficult to identify job classifications or codes in which employees will definitively have an occupational exposure to blood or OPIM: most employees with hospital or clinic-based jobs will have an occupational exposure but most of these individuals work for UHealth and are not covered by this ECP. This belief is based, in part, on the specific nature and variety of exposure activities conducted at the university. **Therefore, it is the responsibility of supervisors to identify each individual (e.g., student, employee) with the potential for exposure to bloodborne pathogens or OPIM and keep a**

current list in the laboratory or facility. This list should contain the tasks and procedures, or groups of closely related tasks and procedures, in which occupational exposure may occur for these individuals.

Note: *Unpaid students may have risk of exposure to bloodborne pathogens or OPIM in the course of participating in their academic program or other University-sponsored activity. The University of Utah is not required to cover the cost for unpaid students to have a hepatitis B vaccine. However, the department is encouraged to adopt a policy that recommends affected students to obtain the vaccine privately and show evidence of this to the department prior to incurring the risk of exposure.*

E. General Laboratory Practices

Detailed laboratory practices for work at BSL-2 are described in the University of Utah Biosafety Manual.

1. Eating, drinking, smoking, applying cosmetics and contact lenses, or storage of foods is not permitted in the laboratory.
2. Personnel must wear the PPE described in their laboratory-specific Exposure Control Plan or Biosafety Manual. At a minimum, they must wear a lab coat, gloves and safety glasses, in conjunction with long pants and solid, closed shoes. PPE must be removed when leaving the laboratory.
3. Personnel must wash their hands and wrists with soap and water after handling infectious material, removal of gloves, and before leaving the laboratory.
4. Control the biohazard area:
    a. Keep laboratory doors and windows closed while work is in progress.
    b. Post a warning sign, such as the universal biohazard symbol, when blood or OPIM is present in the area.
    c. Limit access to the laboratory during procedures involving blood or OPIM. Make sure doors to laboratory are secured and locked at the end of each day.

F. Exposure Minimization

1. Aerosols

Aerosols refer to liquid droplets or solid particulates dispersed in air. Aerosols are too small to

be seen by the unaided eye and remain suspended in air for a period of time. The production of aerosols while handling infectious agents historically accounted for the greatest source of laboratory-acquired infections.

Aerosols may be generated during the use of centrifuges, blenders, shakers, magnetic stirrers, sonicators, serological pipets, pipettors, vortex mixers, syringes and needles, freeze-dried samples, vacuum-sealed samples, mortar and pestles, culture tubes, inoculating loops, and separatory funnels.

a. Perform activities in a biological safety cabinet (chemical fume hood, when appropriate).
b. Keep tubes stoppered when vortexing or centrifuging.
c. Allow aerosols to settle prior to opening centrifuges, blenders, or mixed tubes.
d. Place towels soaked with disinfectant over work surface to deactivate possible spills or droplets of biohazard agents. Soaked gauze can be wrapped around ampoules while breaking, needles while being removed from a vial or stoppers being removed from tubes.
e. When reconstituting or diluting contents of an ampoule do so slowly and carefully.
f. Mix solutions by discharging the secondary fluid down the side of the container or as close as possible to the surface of the primary solution.
g. Allow inoculating needle to cool before touching biological specimens.

2. **Pipetting**
   a. Mouth pipetting is not permitted.
   b. No infectious mixture should be prepared by bubbling air through the liquid with the pipet.
   c. No infectious materials should be forcibly discharged from pipets.

3. **Syringes and needles**
   a. Avoid the use of syringes and needles if possible. Use the needle-locking type or a disposable syringe needle unit.
   b. Needles should not be re-sheathed, bent, broken or removed from disposable syringes. Needles and syringes should be discarded directly in biosafety labeled sharps containers. Do not discard needles into disinfectant pans containing pipets or other glassware.
   c. EHS has developed Fact Sheets on "Sharps Protection for Researchers" and "Examples of Sharps Protection."

G. Training

All university employees with a potential exposure to blood or OPIM are required to participate in a bloodborne pathogens information and training program, which is provided at no cost to the employee and conducted during their normal working hours.

Training must be provided at the time of initial assignment and annual training will be provided within one year of their previous training. Additional training will be provided when changes or modifications of tasks or procedures occur or when new tasks or procedures affect an individual's potential for exposure. The additional training will be limited in scope by only addressing the new exposure created.

1. General Bloodborne Pathogens Training

General Bloodborne Pathogens Training will be provided to all individuals whose job classifications have been identified that may have a reasonably anticipated occupation exposure to Bloodborne pathogens or OPIM and will consist of:

a. An overview of the University of Utah Exposure Control Plan.
b. A general explanation of the epidemiology and symptoms of bloodborne diseases and a review of modes of transmission.
c. Information on how to access the current OSHA Bloodborne Pathogen Standard.
d. Information on how to access the current version of the University of Utah Exposure Control Plan.
e. An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and OPIM.
f. Training in methods to prevent or reduce exposure including appropriate engineering controls, work practices, proper use of signs, and proper use and limitations of PPE.
g. Information on the hepatitis B vaccine, provided at no cost to the employee, including details on its efficacy, safety, method of administration, and the benefits of being vaccinated.
h. Information on proper procedures following an exposure incident, including methods of reporting the incident, medical follow-up that will be made available, and the post-exposure evaluation and follow-up.
i. Information on proper procedures following an environmental exposure or spill including contamination of PPE.
j. Annual refresher training within one year of previous training.

2. Task-Specific Training

Supervisors are required to provide employees with training and information to ensure that employees are apprised of the specific hazards present in their particular area of work. The training requirements include:

a. At a minimum, employees shall be informed of the applicable details of the University of Utah Exposure Control Plan and the specific hazards of the tasks and procedures which may expose them to bloodborne pathogens and OPIM in their work setting, which must be described in a facility-specific Exposure Control Plan.
b. Employers must provide additional training when changes, such as modification of tasks or procedures or institution of new tasks or procedures, affect the employee's occupational exposure. The additional training may be limited to addressing the new exposures created.

3. Training for HIV/HBV/HCV Research Laboratories

Laboratory employees in HIV, HBV, or HCV research laboratories will receive specialized initial training in addition to the established bloodborne pathogens training program. Additional elements of the expanded HIV, HBV, and HCV training program will include:

a. Provisions for the supervisor to verify that employees demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with HIV, HBV, or HCV.
b. Provisions for the supervisor to verify that employees have prior experience in the handling of human pathogens or tissue cultures before working with HIV, HBV, or HCV.
c. Provisions for the supervisor to provide a training program to employees who have no prior experience in handling human pathogens. Initial work activities shall not include the handling of infectious agents. A progression of work activities shall be assigned as techniques are learned and proficiency is developed. The supervisor will ensure that employees participate in work activities involving infectious agents only after proficiency has been demonstrated.

4. Training Records

EHS provides general bloodborne pathogens training and serves as the custodian of all bloodborne pathogens standard training records taken through Bridge: links to training sessions can be found here. These training records are maintained for a minimum of three years from the date on which

the training occurred. All training records required by this standard will be provided upon request for examination and copying to all employees, employee representatives, the Director of the National Institute for Occupational Safety and Health (NIOSH), and the Assistant Secretary of the U.S. Department of Labor in accordance with 29 CFR 1910.20.

Training records will include the following information:

a. The dates of the training session;
b. The contents or a summary of the training sessions;
c. The names and qualifications of persons conducting the training; and
d. The names and job titles of all persons attending the training sessions.

The University of Utah must comply with the requirements involving transfer of records set forth in 29 CFR 1910.20(h). Should the University of Utah cease to do business and there is no successor employer to receive or retain the records for the prescribed period, the University will notify the NIOSH Director at least three months prior to their disposal and transmit them to the NIOSH Director, if required by the Director to do so, within the three-month period.

H. Labels and Signs

All required labels and signs shall include the international biohazard symbol and the word “biohazard” or “biological hazard.” The color must be predominantly orange or orange-red with the lettering and universal biohazard symbol in a contrasting color (see image).

Warning labels must be affixed to:

- Containers of biohazardous wastes.
- Containers used to store, transport, or ship blood or OPIM.
- Refrigerators and freezers where blood or OPIM are stored.
- Incubators used for primary cell cultures.
- Centrifuges and biosafety cabinets when used for work with blood or OPIM.

Warnings signs must be placed at the entrance to all spaces that contain bloodborne pathogens. The signs must include:

- The biosafety level for the room (e.g., research with human blood must be conducted at BSL-2 or higher).

- The name(s) of the biohazardous material that is present.
- The name and telephone number of the principal investigator, laboratory manager, or other responsible individual.
- The procedures for entering and exiting the room.
- Personal Protective Equipment to be worn while in the room.

Each department is responsible for purchasing their own biohazard bags and labels. Some waste containers, including sharps containers can be obtained from EHS through the SAM System, or can be purchased.

Contaminated equipment scheduled for maintenance or repair will be labeled in accordance with the provisions in this section and the label will also state which portions of the equipment remain contaminated. **Note: Biological Safety Cabinets must be decontaminated by an NSF-certified technician prior to servicing or to being moved: contact Biosafety@EHS.Utah.edu for assistance.**

I. Personal Protective Equipment (PPE)

Personal protective equipment is specialized clothing or equipment worn by an employee for protection against a hazard. PPE includes, but is not limited to, gloves, protective laboratory coats or gowns, eye and face protection, and respiratory protection. The types of PPE to be worn in the lab must be described in the laboratory ECP and/or Biosafety Manual. In addition to the specified PPE, all employees in the lab must wear long pants and closed/solid shoes when they are in the lab: no skirts, shorts, or sandals. All skin below the neck must be covered.

Each supervisor must provide the appropriate PPE in the immediate work area for employees to take the necessary precautions to prevent or reduce exposure to bloodborne pathogens or OPIM. PPE should be selected only after a hazard assessment has been performed and shall not be considered unless other means of controls have been evaluated, including engineering or substitution of less hazardous materials or processes. The supervisor must provide for the cost of obtaining, maintaining, replacing, and disposing of PPE. For assistance with PPE selection, contact EHS.

Always wash hands and wrists immediately, or as soon as feasible, after removing gloves and other PPE. Hands and wrists must be washed with warm water and soap for at least 20 seconds. Never reuse disposable gloves. Remove PPE after it becomes contaminated and before leaving the work area. PPE, including lab coats and gloves, must not be worn in public areas such as the bathrooms, elevators, break rooms or general office areas. All disposable PPE must be discarded in biohazard waste containers and all biohazardous waste policies must be followed.

Personal Protective Equipment	
Type of PPE	**Safety Information**
Gloves	Gloves must be worn to protect hands from exposure to bloodborne pathogens or OPIM. Gloves must be changed when contaminated, integrity has been compromised, or when otherwise necessary. Double gloving is recommended, particularly when working with pathogenic microorganisms and when cleaning up spills. Vinyl gloves are not appropriate. Heavy rubber gloves may be needed when decontaminating equipment or cleaning spills. Utility gloves may be decontaminated and reused but must be discarded when cracked or torn. Gloves must be removed and hands and wrists washed when work with bloodborne pathogens or OPIM has been completed and before leaving the laboratory. Do not wash or reuse disposable gloves. Dispose of used gloves with other contaminated laboratory waste.
Eye and Face Protection	Eye and face protection (impact resistant safety glasses with temple and side protection, or goggles) must be used 1) for anticipated splashes or sprays of bloodborne pathogens or OPIM, and 2) when the microorganisms are handled outside the Biological Safety Cabinet (BSC) or physical containment device. Face shields or face masks may also be worn, but safety glasses or goggles must also be worn. Personnel who wear contact lenses must always wear eye protection in laboratories. Eye and face protection must be used in rooms containing infected animals.
Laboratory Coats	Protective laboratory coats, gowns, smocks, or uniforms must be worn while working with bloodborne pathogens or OPIM. This protective outerwear protects skin surfaces and street clothing from contamination. Disposable water-resistant gowns must be used when working with materials which may splash or splatter. Lab coats with cuffed sleeves or disposable sleeve covers are recommended. Contaminated protective outerwear must be removed and replaced as soon as possible.
Respiratory Protection	Any use of respiratory protection (e.g., N95, half-mask, full-face respirators) requires a medical clearance, written respiratory protection plan and fit test, which is conducted by EHS.

J. Work Practices

Work practices are methods and procedures followed by employees to protect themselves from exposure. The following work practices are derived from the OSHA standard:

Handwashing	The number one defense against infection is clean hands. Hands and wrists shall be washed with soap and running water for at least 20 seconds after removing gloves or other PPE and before leaving the work area. If a sink is not available, hands and wrists shall be cleaned with disinfectant wipes or alcohol-based sanitizer, containing at least 60% alcohol) and washed with soap and water as soon as a sink becomes available. Overly vigorous hand washing is not recommended, as it may cause skin breaks or abrasions and chapped hands.
Sharps/ Containers	The use of syringes and needles, glass Pasteur pipettes, and other sharps such as scalpels, razors, and suture needles should be minimized. Replace glass with plastic whenever possible. Used sharps and contaminated broken glassware, pipets and pipet tips must be disposed into sharps containers as soon as possible. The sharps containers shall be labeled with the universal biohazard symbol, and shall be puncture-resistant, leak-proof, and closable for transport. Non-contaminated broken glassware, pipets and pipet tips must be disposed into broken glass containers. Containers must be located where sharps can be disposed of immediately after use.
Work Area Restrictions	Eating, drinking, chewing gum, smoking, applying cosmetics, and handling contact lenses are prohibited in areas where blood and OPIM are handled or stored. Phones and headphones must not be used in areas where blood and OPIM are handled or stored. Food and drinks must not be kept in freezers, refrigerators, and other places used to handle or store OPIM, and must be kept outside the laboratory. Areas where blood and OPIM are stored or worked with must be posted with hazard identification (such as the universal biohazard symbol) to ensure all personnel entering the area aware of the potential hazards present. Pets are not allowed in the laboratory: ADA service animals may be accommodated with Office of Equal Opportunity (OEO) approval.
Specimen Handling/ Transport	Specimens and other materials to be transported between work sites must be placed in a secondary container that is leak-proof and labeled with the universal biohazard symbol. Containers for shipping specimens must meet

	the Department of Transportation and United States Postal Service requirements. Shipping of Category B biological materials and items requiring dry ice must only be performed by personnel trained by EHS: Category A biological materials must be shipped by EHS personnel. International shipping may require permits or authorization from the United States Department of Agriculture or Centers for Disease Control. Contact EHS for more information.
Contaminated Equipment	Equipment used to store or handle blood and OPIM shall be labeled with the universal biohazard symbol. It must be cleaned and decontaminated before being serviced, repaired, or transported from the work area: biological safety cabinets must be decontaminated by an NSF-certified technician (contact EHS for assistance). Any parts of the equipment that cannot be decontaminated should be labeled with the biohazard symbol and the information communicated to all affected people.

K. Housekeeping

Bench tops, counters, and all other equipment used to work with blood and OPIM must be disinfected after completing activities, at the end of the workday, when work surfaces are overtly contaminated, or after any spill. Commonly used disinfectants include a freshly prepared 1:10 dilution of household bleach. Other suitable disinfectants are provided in the table below but must be EPA-registered: see **Appendix F**.

Work surfaces and equipment may be covered to prevent contamination with infectious materials. Protective coverings should be removed and replaced at the end of the work, after a spill, or when they are overtly contaminated. Coverings must be discarded as biological waste.

A schedule to clean floors, sinks and equipment must be established and described in the facility ECP. Regardless of schedule, any spill of blood or OPIM must be cleaned up immediately.

Chemical Disinfectants*		
Disinfectant	**Working Solution**	**General Use**
Bleach (Sodium Hypochlorite)	1:10 dilution of commercial bleach solution (0.5% sodium hypochlorite). Should be freshly prepared.	Disinfects work areas, floors, walls, glassware. Good general all around disinfectant. Disinfects liquid cultures for disposal.
Quaternary Ammonia (Commercial Grade)	10-100 ppm	Disinfects floors, work surfaces, glassware.
Phenolics (Commercial Grade)	2.8-3.0% Active Ingredient	Disinfects instruments, and work surfaces.
Glutaraldehyde	2-3%	Disinfects instruments, including endoscopic tubes.
Iodophor	75-150 ppm	Disinfects instruments and surfaces, non- corrosive.

*Contact EHS for more information about chemical disinfectants or see Appendix F. Refer to the Environmental Protection Agency (EPA) website for a list of approved chemical disinfectants.

L. Biological Spill Kits

Biological spill kits should be available wherever blood or OPIM are used or stored: kits are available for purchase from EHS. The contents of the biological spill kit include:

- Bleach or other EPA-registered disinfectant. Non-diluted bleach should be replaced 6 months after purchase
- Biohazard bag
- Disposable lab coat
- Disposable shoe covers
- Hand sanitizing wipes
- Nitrile gloves (4 pair/multiple sizes)
- Mini brush and dustpan (or something to scoop spilled materials)
- Paper towels or other absorbent material

- Safety glasses or goggles
- Face mask or shield (safety glasses or goggles must still be worn)
- Tong or forceps to pick up broken glass
- Spray bottle (to make fresh bleach solution)
- Rigid, leak-proof container for sharps
- "Biohazard Spill" and/or "Do Not Enter" sign

M. Spills

Spills of blood or OPIM must be cleaned up immediately by personnel trained in the hazards associated with bloodborne pathogens (and be familiar with this plan) using the following procedures:

1. Spill clean-up procedures shall be posted in a location that is easily accessible prior to beginning work.
2. For large spills (>10ml), inform personnel in the area and evacuate: wait 30 minutes for aerosols to settle. Post signs prohibiting unauthorized entry.
3. Wear proper PPE, including lab coat, two pairs of gloves, shoe covers, and eye protection: other specialized clothing, such as disposable Tyvek™ suits, sleeve covers, N95 respirators may be required depending on the nature of the work.
4. If possible, isolate the spill and cover it with towels or absorbent pads.
5. Pour a freshly prepared 1:10 solution of Clorox bleach and water (1-part bleach to 9 parts water: approximately 0.5% sodium hypochlorite) or other EPA-registered disinfectant on the spill, working inward toward the center of the spill and let it stand for 20 minutes. This allows the disinfectant time to kill the organisms present.
6. Use mechanical means such as tongs or a scoop to pick up broken glassware or sharps, and dispose them in a sharps container. Sharps must never be handled with bare hands.
7. Remove the towels and spray the area with disinfectant: allow to air dry. To remove disinfectant residue rinse with water or a mild soap solution.
8. Clean non-disposable tools with an appropriate disinfectant.
9. Dispose of disposable waste products in the biohazard waste containers.
10. Wash hands and wrists with soap and water. Inform colleagues that it is safe to enter the facility.

Detailed Spill Clean Up Procedure Templates are provided in **Appendix B**. These should be adapted and posted in the laboratory.

N. Post Exposure Procedures

Exposures include:

1. Direct skin, eye or mucosal membrane exposure to blood or OPIM, such as tissue culture media or cells, bodily fluids from humans or infected animals.
2. Parenteral inoculation by a syringe needle or other contaminated sharp (needlestick),
3. Ingestion of liquid suspension of an infected material or by contaminated hand to mouth exposure, or
4. Inhalation of infectious aerosols.

In the event of an exposure, follow these steps immediately:

1. Remove exposed PPE taking care to avoid contact of unexposed areas to infectious agents on the PPE.
2. Inform others in area about any biohazardous materials out of containment to prevent further exposure. If possible, contain with absorbent pads, decontaminate with bleach, and/or seal off the site, as described above. **ALL exposed individuals must leave the area.**
3. Immediately wash affected areas with soap and water, or if exposure to eyes or mucous membranes occurred, immediately flush affected area with water for 10-15 minutes.
4. For serious/life threatening exposures or chemical burns, call 911.
5. After washing, notify lab supervisor or Principal Investigator of the exposure if they are immediately available. If not seek medical attention first and then report the exposure to them later.
6. Employees go immediately to the RedMed Employee Health Clinic at the University Union Building or the Occupational Medical Clinic at the Redwood Health Center, while students go to the Student Health Center at the Madsen Clinic, for medical evaluation and follow-up; contact information is below. After 5pm you will be seen by an Urgent Care Physician at the Redwood Health Center. After 9pm, go to the University of Utah Hospital Emergency Department or call an ambulance (911).
7. Ensure that the physician is aware of all materials that were being used at the time of exposure (e.g., human blood, virus, bacteria, human tissue, animal tissue, other potentially infectious material).
8. Follow up with the physician at Occupational Medicine, as requested.
9. **Post exposure prophylaxis must be initiated as soon as possible after exposure, if indicated.**

10. Inform the Healthcare Provider of any medical conditions, such as pregnancy or immunosuppression, or drug treatment that you currently have or take. The Healthcare Provider must have this information to evaluate and develop a proper post treatment evaluation.

11. Upon returning to work, fill out the Employers First Report of Injury or Illness E1 Form. This form can be downloaded from the human resources website under "Forms" (https://www.hr.utah.edu/forms/index.php).

12. After medical care, ensure that the incident is immediately reported to the Biosafety Officer (801-581-6590).

13. Have the PI/Supervisor contact the Biosafety Officer (801-581-6590) as soon as possible. If the project involves recombinant and synthetic nucleic acid molecules, the IBC will be required to report any significant problems with or violations of the NIH Guidelines for Research with Recombinant or Synthetic Nucleic Acid Molecules and any significant research-related accidents or illnesses to the NIH within 30 days.

RedMed Employee Health Clinic
200 Central Campus Dr.
Salt Lake City, UT 84112
Phone: (801) 213-3303
Hours: M-TH: 8:00AM – 5:00PM, Friday: 9:00AM – 3:30PM
Closed 1.30PM-2PM

Redwood Health Center
Occupational Medicine Clinic
1525 West 2100 South
Salt Lake City, UT 84119
Phone: (801) 213-9777
Hours: M-F 8:00AM – 5:00PM

After Hours
Redwood Urgent Care
1525 West 2100 South
Salt Lake City, UT 84119
M-F 5:00PM – 8:30PM
Sat.-Sun.: 9:00AM – 8:30PM
(801) 213-9700

After 8.30 PM

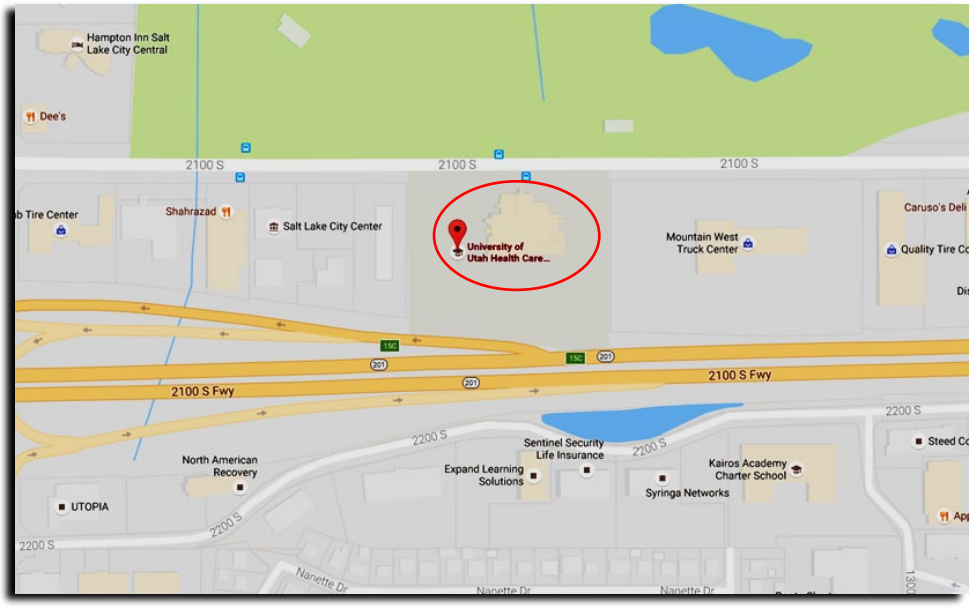
Emergency Department at University Hospital
(main floor, northeast side of the hospital)
50 N. Medical Drive
Salt Lake City, UT 84132
(801) 581-2292

Maps of Occupational Medicine Clinics

REDMED EMPLOYEE HEALTH CLINIC

200 Central Campus Dr. Salt Lake City, UT 84112

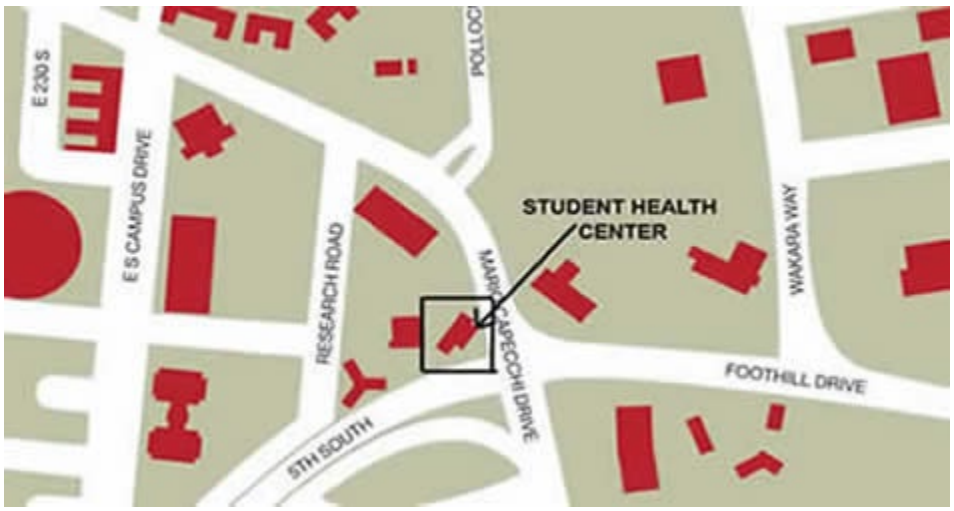
Maps of Occupational Medicine Clinics



UNIVERSITY OF UTAH REDWOOD HEALTH CENTER OCCUPATIONAL MEDICINE

1525 W. 2100 S. Salt Lake City UT, 84119

NOTE Students who do not receive compensation from the University shall go to the Student Health Center at the Madsen Clinic in non-emergency situations. For emergencies, call 911.



555 Foothill Dr. Level 1
Salt Lake City, UT 84112
Phone: 801-581-6431
Fax: 801-585-5294

Hours

- Operating Hours: Monday-Friday, 7:30 am to 5 pm
- Appointment Hours: Monday-Friday, 8 am to 4 pm
- Walk-in (vaccines, lab tests) Hours: Monday-Friday, 9 am to 4 pm

Note: Clinic is closed on Wednesdays, 12-2pm.

Extended Hours

- Tuesdays, evening appointments to 6:30 pm
- Fall and Spring Semesters only
  - Tuesday, 7:30 am to 7:30 pm
  - Saturday, 9:00 am to 12:00 pm

Note: Extended hours do not apply to Tuesdays or Saturdays during or near breaks/holidays.

After-Hours Care

University of Utah Health Care Urgent Care centers provide extended hours for general care (http://healthcare.utah.edu/primarycare/urgent.php). Alternatively, call 801-581-6431 for recorded directory information.

Upon returning to work, contact Risk Management at 801-581-5590.

O. Post-Exposure Evaluation and Follow-Up

Following a report of an exposure incident, the employee shall be provided a confidential medical evaluation and follow-up. This follow-up must include documentation of the route(s) of exposure and the circumstances under which the exposure incident occurred, identification and testing of the source individual's blood if available, collection and testing of the employee's blood, post-exposure prophylaxis (when medically indicated), evaluation of reported illnesses, and counseling. The University of Utah will provide this evaluation and follow-up through the University of Utah Occupational Medicine Clinic or contracted health care providers at no cost to the employee.

1. Documentation of the Source Individual

The source individual will be identified if feasible unless prohibited by federal, state or local law:

a. The source individual's blood shall be tested as soon as feasible and after consent is obtained, in order to determine HBC, HCV and HIV infectivity; the results will be documented.
b. When the source individual is already known to be infected with HBV, HIV, or HCV, testing for the source individual's known HBV, HIV, or HCV status need not be repeated.
c. Results of the source individual's testing shall be made available to the exposed employee, and the employee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.
d. If an aliquot of the sample that was the cause of the exposure is still available it may be possible to test directly for HBC, HCV and HIV. However, if there is any means by which the sample can be linked to a person, such as a sample that is not de-identified or it is coded in such a way that it is feasible to still identify the source (for example, through a database linking the code with the person), then consent must be obtained prior to testing.

2. Blood Collection and Testing

The exposed employee's blood must be collected no later than 10 calendar days after the exposure incident. Serological testing for HIV, HBV, and HCV will be performed after consent is obtained; a healthcare professional's written opinion will be made available within 15 days after completion of the evaluation. Testing must be completed no later than 30 calendar days after the exposure incident. No later than 18 months after the date of the exposure incident, the employee will be retested. If an employee chooses not to complete the testing, that employee may jeopardize the availability of worker's compensation benefits.

3. Information Provided to the Health Care Provider

The health care professional responsible for the employee's hepatitis B vaccination will have access to the OSHA Bloodborne Pathogens Standard. The health care professional evaluating an employee after an exposure incident will be provided the following information:

- A description of the exposed employee's duties as they relate to the exposure incident.
- Documentation of the route(s) of exposure and circumstances under which exposure

occurred.

- Results of the source individual's blood testing, if available.

4. Health Care Professionals Written Opinion

The supervisor will obtain and provide the employee with a copy of the evaluating health care professional's written opinion within 15 days of the completion of the evaluation. The health care professional's written opinion for hepatitis B vaccination will be limited to whether hepatitis B vaccination is indicated for an 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 the following information:

- That the employee has been informed of the results of the evaluation.
- That the employee has been told about any medical conditions resulting from exposure to blood or OPIM which require further evaluation or treatment.
- All other findings or diagnoses will remain confidential and will not be included in the written report.

5. Evaluation of Incident

The circumstances surrounding the exposure incident must be investigated immediately by the supervisor. Information regarding the exposure incident, source material, and employee vaccination status should be provided to the University of Utah Occupational Medicine and/or the employee's health care provider. Site-specific procedures should be reevaluated and revised as necessary to prevent recurrences of similar incidents. EHS is available to assist you with evaluating the following:

a. Engineering controls and work practices used at the time of the exposure.
b. A description of any devices being used (e.g., sharps, centrifuge, blender).
c. Protective equipment or clothing worn at the time of the exposure incident.
d. A review of the procedures being performed at the time of the incident.
e. A review of the employee's training record.

P. Documentation and Recordkeeping

1. Medical Recordkeeping

The University of Utah Occupational Medicine Clinic will establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.1020. The record shall include:

1. The name and employee identification number of the employee.
2. A copy of the employee's hepatitis B vaccination status, including the dates of all the hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination.
3. A copy of all results of examinations, medical testing, and follow-up procedures required.
4. The copy of the healthcare professional's written opinion as required.
5. A copy of the information provided to the healthcare professional as required.

The University of Utah Occupational Medicine Clinic will ensure that employee medical records required 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 the standard or as may be required by law. The University of Utah Occupational Medicine Clinic will maintain the records required for at least the duration of employment plus thirty years in accordance with 29 CFR 1910.1020.

2. Employee Records

The University of Utah is required to establish and maintain an accurate record for each employee with an occupational exposure, in accordance with 29 CFR 1910.1020. This record is maintained by the University of Utah Occupational Medicine Clinic and includes:

1. The name and social security number of the employee.
2. A copy of the employee's hepatitis B vaccination status including the dates of all the hepatitis B vaccinations and any medical records relative to the employer's ability to receive vaccination.
3. All medical records pertaining to an exposure incident and follow-up evaluation. All documentation will be held under strict confidentiality guidelines.

3. Sharps Injury Log

The University of Utah is required to establish and maintain a sharps injury log (see **Appendix C**) for the recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee. The sharps injury log is maintained by each supervisor. The sharps injury log must contain the following information:

a. The type and brand of device involved in the incident.
b. The laboratory in which the exposure occurred.
c. An explanation of how the incident occurred and personnel involved.

4. Documentation of Updated Safe Practices

Consideration of changes in technology that reduce or eliminate exposure must be evaluated and documented annually (**Appendix D**), including solicitation of input from non-managerial staff.

5. OSHA Recordkeeping

Human resources will evaluate all incident reports to determine if cases meet OSHA's Recordkeeping Requirements (29 CFR 1904). All percutaneous injuries from contaminated sharps are also recorded in the Sharps Injury Log (**Appendix C**).

Q. Laboratory Biological Waste Disposal

This section describes procedures for the proper handling and disposal of biological waste from research, instructional, and clinical laboratories at the University of Utah. These procedures are based on state and federal law, requirements from the Occupational Safety and Health Administration (OSHA), Centers for Disease Control (CDC) and National Institutes of Health (NIH), and good laboratory practice. Failure to manage biological waste properly could result in personal injury, disruption to research, fines, or criminal prosecution.

1. Biowaste Disposal – Solids

a. The Office of Environmental Health and Safety (EHS) SAM System allows research investigators to request hazardous material pickups by EHS staff and request empty containers.
b. Waste containers obtained from EHS are solid sided, leak proof, lined with red biohazard

bags, and labeled with a biohazard symbol. Keep the container lid closed unless someone is working nearby and regularly adding waste to the container.

c. When the red bag is ¾ full, loosely tie or tape the bag closed. Secure the lid on the waste container and move it to a convenient storage location or transport it to a biohazardous waste storage room, if available. Biohazardous waste must be moved or transported inside a rigid, leak-resistant, labeled container with the lid closed. Request a pickup from your lab using the SAM System. If you have an autoclave available for disinfection of biohazardous waste, place a red biohazard bag in a solid puncture resistant container. Place a Ziploc bag or balloon containing water in the bag when it is about half full to generate steam during autoclaving. When the red bag is full, loosely tie or tape the bag closed. Secure the lid on the waste container and move it to the autoclave room.

   i. Note: Autoclaves used for decontamination of biological waste must be tested using a biological indicator weekly or every 40 hours, whichever is less frequent. EHS has guidance documents on autoclave use and testing.

d. The bag must be removed and placed in a solid autoclave resistant tray: the bag should **NEVER** be placed directly on the floor. After the cycle, the bag may be disposed of as regular trash: indicators that the contents have been autoclaved must be present.

2. Biowaste Disposal – Liquids

- Blood, aspirated tissue culture media, or other liquid waste generated from BSL-2 experiments must be disinfected and then disposed. Bleach is typically used to disinfect liquids, but other agents, such as ZZZ or Vesphene III se, may be used if effective.
- If you use bleach:
  - Ensure the final concentration exceeds 0.5% sodium hypochlorite (no less than one-part bleach to 9 parts liquid).
  - Ensure the bleach is fresh: in tissue culture media traps change at least twice weekly. Undiluted bleach stocks should be replaced every 6 months.
  - Ensure the media is exposed to disinfectant for at least 20 minutes prior to disposal.
  - Dispose down the sink with running water
- If you use ZZZ or Vesphene III se:
  - Ensure the final concentration exceeds 400ppm (one part disinfectant to 99 parts water).
  - In tissue culture media traps change at least every 3 months (indicate the date of the last change on the flask). Check the expiration date on the disinfectant stock bottle.
  - Ensure the media is exposed to disinfectant for at least 20 minutes prior to

disposal.

- Collect waste into containers marked “Unwanted Materials” and date when you start collecting. When full or 6 months after your start date (whichever happens first), arrange pickup by EHS through the SAM System. **NO DRAIN DISPOSAL** without prior EHS approval**.**
- If the container will be unattended (outside of your immediate control) then label it with the date, time and the words “Biohazardous liquid” and keep it in a secondary container (for example, a plastic tub) while it is disinfecting.

- If you use other agents to decontaminate liquid cultures follow the instructions on the packaging. Contact the Biosafety Officer (801-581-6590) for advice on appropriate disinfectants and procedures for disposal of treated waste.
- Mixed liquid and solid waste should be separated in a biosafety cabinet (decant the liquid from the solid). Manage the liquids and solids separately as detailed above.

3. Use and Disposal of Sharps

- Do not recap needles by hand. RECAPPING OF NEEDLES IS PROHIBITED.
- Do not remove needles from syringes by hand.
- Do not bend, break, or otherwise manipulate needles by hand.
- Avoid using needles whenever possible.
- Replace glass materials with plastic (such as plastic Pasteur pipettes) whenever possible.
- Immediately after use, discard needle and syringe (whether contaminated or not) into puncture resistant sharps containers. RECAPPING OF NEEDLES IS PROHIBITED.
- Use a Food and Drug Administration (FDA)-cleared sharps container if you generate sharps waste (pictured below). A description of FDA-Cleared Sharps containers can be found here. FDA-cleared sharps disposal containers are made from rigid plastic, come marked with a line that indicates when the container should be considered full, which means it’s time to dispose of the container, and have the Universal Biohazard symbol.

- Never discard sharps into regular trash.
- Never discard sharps into bags of biological waste.
- Use care and caution when cleaning up after procedures that require the use of syringes and needles.
- Do not overfill sharps containers. Close completely when 3/4 full, request pickup from the EHS through the SAM System.
- Locate sharps containers in areas in which needles are commonly used. Make containers easily accessible.
- Replacement sharps containers may be obtained through the SAM System or can be from laboratory supply distributors, such as VWR and ThermoFisher. Be sure to select sharps containers that withstand autoclaving.

4. Contaminated Serological Pipets and Pipet Tips

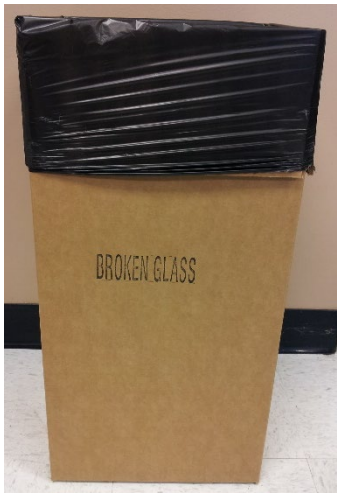
Serological pipets (glass and plastic) and disposable pipet tips are considered puncture hazards and should be disposed of as sharps. Contaminated pipets and tips should be discarded in approved sharps containers, as described above.

Due to the large size of serological pipets, investigators disposing of large numbers of these can request 20 gallon hard-sided biohazard waste containers (pictured below) from EHS through the SAM System. These will be picked up by EHS staff as for other biohazardous waste.

20 Gallon Waste Container

5. Decontaminated Serological Pipets and Pipet Tips

It is possible to decontaminate serological pipets and tips prior to disposal. Ensure that both the inside and outside of the pipets or tips are exposed to the approved disinfectant (e.g. a freshly prepared 1:10 dilution of bleach) for at least 20 minutes. However, serological pipets and disposable tips are still considered puncture hazards. Therefore, after removing the disinfectant, they can be disposed of in a Broken Glass box (rigid puncture resistant boxes lined with a plastic bag and labeled “Broken Glass”: pictured below), which can be obtained from your custodial staff or from EHS. Once they are 3/4 full they should be closed with tape and disposed as regular trash by your custodians.



Broken Glass Box

R. Laundry

The University of Utah School of Medicine can be used to clean contaminated clothing and other articles that require laundering. Linen Services can be found in the Acute Care Building in the University Hospital, 801-581-2200. Alternatively, there are commercial laundry services that can clean contaminated lab coats, such as Cintas, Alsco and Aramark.

The following laundering requirements must be met:

- Handle contaminated laundry as little as possible, with minimal agitation.
- Place wet contaminated laundry in leak-proof, labeled or color-coded containers before transport to the University Hospital Laundry.
- Contact outside providers for information on their transport requirements.

S. Definitions

Blood: Human blood, or non-human primate blood, blood components, and products made from human or non-human primate blood.

Bloodborne Pathogens: Pathogenic microorganisms that are present in human or non-human primate blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) hepatitis C (HCV), and human immunodeficiency virus (HIV).

Clinical Laboratory: A workplace where diagnostic or other screening procedures are performed on blood or OPIM.

Collateral Duty Exposure: Exposure to blood or OPIM during first aid activities rendered by an individual whose primary job assignment is not the rendering of first aid or other medical assistance. Typically individuals with collateral duty exposure to blood or OPIM respond solely to injuries resulting from workplace incidents, generally at the location where the incident occurred.

Contaminated: The presence or the reasonably anticipated presence of blood or OPIM on an item or surface.

Contaminated Laundry: Laundry which has been soiled with blood or OPIM or may contain

sharps.

Contaminated Sharps: Any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, pipets and pipet tips, and exposed ends of dental wires.

CPR: Abbreviation for cardiopulmonary resuscitation. An emergency medical procedure for a victim of cardiac arrest or, in some circumstances, respiratory arrest.

Decontamination: The use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

Designated First Aid Responder: An individual who is trained in first aid and identified by the University of Utah as responsible for rendering medical assistance as part of his/her job duties. An individual who routinely provides first aid with the knowledge of the department or supervisor is also considered a designated first aid responder even if providing first aid is not officially in the employee's job description.

Engineering Controls: Controls (e.g., sharps disposal containers, self-sheathing needles, safer medical devices, such as sharps with engineered sharps injury protections and needleless systems) that isolate or remove the bloodborne pathogens hazard from the workplace.

Exposure Incident: A specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or OPIM that results from the performance of an employee's duties.

Handwashing Facilities: A facility providing an adequate supply of running potable water, soap, and single-use towels or air-drying machines.

Licensed Healthcare Professional: A person whose legally permitted scope of practice allows him or her to independently perform Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up.

HBV: Hepatitis B virus.

HCV: Hepatitis C virus.

HIV: Human immunodeficiency virus.

Needleless Systems: A device that does not use needles for: (1) The collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established; (2) The administration of medication or fluids; or (3) Any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

Occupational Exposure: Reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or OPIM that may result from the performance of an employee's duties.

EHS: Abbreviation for the University of Utah Department of Occupational and Environmental Health and Safety. The telephone number is 801-581-6590.

Other Potentially Infectious Material or OPIM: (1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any 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: (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV, HBV, or HCV; and (4) All primary human and non-human primate cell explants from tissues and subsequent in vitro passages of human or primate tissue explant cultures (including established cell lines), unless characterized by documented, reasonable laboratory testing to be free of HIV, HBV, HCV, and other bloodborne pathogens..

Parenteral: Piercing mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, and abrasions.

Personal Protective Equipment or PPE: Specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment.

Production Facility: A facility engaged in industrial-scale, large-volume or high concentration production of HIV, HBV, or HCV.

Regulated Waste: Liquid or semi-liquid blood or OPIM; contaminated items that would release blood or OPIM in a liquid or semi-liquid state if compressed; items that are caked with dried blood or OPIM and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or OPIM.

Research Laboratory: A laboratory producing or using research-laboratory-scale amounts of HIV, HBV, or HCV. Research laboratories may produce high concentrations of HIV, HBV, or HCV but not in the volume found in production facilities.

Sharps: Engineered sharps injury protection means a non-needle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.

Source Individual: Any individual, living or dead, whose blood or OPIM may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinic patients; clients in institutions for the developmentally disabled; trauma victims; clients of drug and alcohol treatment facilities; residents of hospices and nursing homes; human remains; and individuals who donate or sell blood or blood components.

Sterilize: The use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.

Student: A registered University of Utah student participating in academic programs or University-sponsored activities (e.g., athletics) that have been identified by EHS as subject to exposure risk, and/or to the extent that their exposure occurs in the course of such participation.

Universal Precautions: An approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens. It does not apply to feces, nasal secretions, sputum, sweat, tears, urine or vomitus unless they contain visible blood.

Work Practice Controls: Controls that reduce the likelihood of exposure by altering the

manner in which a task is performed (e.g., prohibiting recapping of needles by a two- handed technique).

T. References

29 CFR 1910.1030 – OSHA Bloodborne Pathogen Standard

University of Utah Institutional Biosafety Committee

CDC Biosafety in Microbiology and BioMedical Laboratories, 6th Edition

CDC Hepatitis B Fact Sheet

CDC Hepatitis C Fact Sheet

CDC Bloodborne Infectious Diseases

OSHA - Applicability of Bloodborne Pathogen Standard to Established Human Cell Lines

OSHA - Bloodborne Pathogen Fact Sheets

OSHA - Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens

OSHA - Most Frequently Asked Questions about the Bloodborne Pathogen Standard

OSHA - Needlestick Prevention Site

OSHA - Universal Precautions

Public Health Agency of Canada: Pathogen Safety Data Sheets and Risk Assessment

Updated U.S. Public Health Service guidelines for the management of occupational exposures to HIV and recommendations for postexposure prophylaxis.

ACKNOWLEDGEMENTS

This document has been developed from earlier University of Utah ECPs and Standard Operating Procedures (SOP) documents, as well as Exposure Control Plans, Safety Manuals and SOPs developed at other Universities, including Arizona State University, University of California Los Angeles, University of California Berkeley, and templates provided by the American Biological Safety Association.

Appendix A: Cleaning up Spills of Blood or OPIM outside of the laboratory.

All equipment and environmental and working surfaces shall be cleaned and decontaminated immediately after contact with blood or other potentially infectious materials.

1. If an exposure incident has occurred follow the proper procedure for any exposed personnel – exposed personnel should not be performing cleanup activities – they should be following the exposure incident procedure

2. Secure area of the spill. Use barricades, tape, cones, etc. to keep unauthorized persons out of the spill area. Make sure to identify all contaminated areas – look for tracking, splatter, etc.

3. Get organized. Identify a "hot" (contaminated) and "cold" (clean) zone. Stage cleanup materials in the cold zone just outside the hot zone. Get the disposal bag ready by turning the top edge downward. This will provide a degree of rigidity for the bag and will keep the exterior of the bag from becoming contaminated. Remember you will have to decontaminate any non-disposable equipment used during the cleanup procedure.

4. Don appropriate Personal Protective Equipment (PPE).

5. Remove any broken glass or other sharps using forceps – DO NOT use your hands!!! Place sharps in a biohazard sharps container for disposal.

6. Apply an absorbent material such as paper towels over the blood or other potentially infected material (identified as "blood" from this point forward in the procedure).

7. Apply a disinfectant solution such as a freshly made solution of 1-part bleach in 9-parts water – saturate the absorbent material such that the solution penetrates the material and soaks into the blood underneath.

8. Allow the saturated absorbent material to sit on the spill for at least 20 minutes.

9. Remove the absorbent material and as much absorbed blood as possible. Place all materials in the disposal bag.

10. Inspect the area for any missed contamination – repeat the cleaning step as many times as needed to completely clean the area.

11. Thoroughly clean the area with up the disinfectant solution and paper towels or other absorbent wipes. Place all materials in the disposal bag.

12. Decontaminate all non-disposable equipment, dispose of contaminated disposable equipment in the disposal bag leaving the gloves for last.

13. Close and secure the disposal bag and place in a secure location.

14. Remove barricades etc. used to secure the spill area.

15. Initiate a hazardous materials disposal request via the EHS website

Procedimiento de respuesta a derrames de patógenos transmitidos por la sangre

1. Si se ha producido un incidente de exposición, siga el procedimiento apropiado para cualquier personal expuesto; el personal expuesto no debe realizar actividades de limpieza; deben seguir el procedimiento de exposición de incidentes

2. Asegure el área del derrame. Use barricadas, cinta adhesiva, conos, etc. para mantener a personas no autorizadas fuera del área del derrame. Asegúrese de identificar todas las áreas contaminadas - busque el rastreo, salpicaduras, etc.

3. Organícese. Identifique una zona "caliente" (contaminada) y "fría" (limpia). Etapa de los materiales de limpieza en la zona fría justo fuera de la zona caliente. Obtener la bolsa de eliminación de listo girando el borde superior hacia abajo. Esto proporcionará un grado de rigidez para la bolsa y evitará que el exterior de la bolsa se contamine. Recuerde que tendrá que descontaminar cualquier equipo no desechable utilizado durante el procedimiento de limpieza.

4. Ponga el equipo de protección personal adecuado (EPP).

5. Retire cualquier vidrio roto u otros objetos punzantes usando una pinza - NO use las manos !!! Coloque los objetos punzocortantes en un contenedor de objetos cortantes de riesgo biológico

para su eliminación.

6. Aplique un material absorbente tal como toallas de papel sobre la sangre u otro material potencialmente infectado (identificado como "sangre" de este punto adelante en el procedimiento).

7. Aplique una solución desinfectante tal como una solución recién hecha de 1 parte de lejía en 10 partes de agua - sature el material absorbente de tal manera que la solución penetra en el material y se sumerge en la sangre por debajo.

8. Deje que el material absorbente saturado se siente sobre el derrame durante al menos 20 minutos.

9. Retire el material absorbente y la mayor cantidad posible de sangre absorbida. Coloque todos los materiales en la bolsa de desecho.

10. Inspeccione el área para detectar cualquier contaminación perdida - repita el paso de limpieza tantas veces como sea necesario para limpiar completamente el área.

11. Limpie completamente el área con la solución desinfectante y las toallas de papel u otras toallitas absorbentes. Coloque todos los materiales en la bolsa de desecho.

12. Descontaminar todo el equipo no desechable, desechar el equipo desechable contaminado en la bolsa de eliminación dejando los guantes para el final.

13. Cierre y asegure la bolsa de desecho y colóquela en un lugar seguro.

14. Retire las barricadas, etc., usadas para asegurar el área del derrame.

15. Inicie una solicitud de eliminación de materiales peligrosos a través del sitio web de EHS

Appendix B: Cleaning up Spills of Blood or OPIM in a laboratory

All spills or breaks involving Recombinant or Synthetic Nucleic Acid Molecules and hazardous biological materials should be cleaned up using appropriate biosafety procedures, described below. If there is any doubt about what to do, call the PI (*Telephone #*), or the Biosafety Officer 1-6590, or the University's internal emergency number: 5-2677.

The following items should be included in a biological spill kit:

- **Disinfectant** – Prepare a fresh 1:10 bleach solution. In other words, a pre-measured amount of bleach in a spray bottle is placed in the spill kit, but the cold water required to dilute the bleach is not added until right before use. Otherwise, use an EPA-registered disinfectant (effective against HIV and HBV) following manufacturer's instructions. Examples are Cavicide, Cidex OPA and Clidox-S. Note the date of manufacture and/or expiration.
- **Absorbent material** (paper towel, absorbent powder)
- **Personal protective equipment** (e.g., disposable gloves (2 pairs), eye protection, face shield or surgical mask, lab coat, shoe covers). It is necessary to review the PPE in the spill kit on a regular basis to verify quality. Gloves can degrade due to exposure to UV or fluorescent lighting, temperature extremes, and the effects of time. At the first sign of degradation (e.g., discoloration, brittleness, stickiness, tearing), replace the gloves in the spill kit with new ones. Likewise, the strap on splash goggles can undergo similar degradative processes.
- **Mechanical tools** (forceps or tongs, broom and dustpan) – Dispose of biohazardous waste after spill response. Purchase inexpensive plastic tools for this purpose.
- **Waste container** (biohazard bags) – By assembling all of the spill materials in a bucket or other leak-proof and puncture-proof container, you will have a secondary container readily available for proper containment of your biohazard bag.

A. Spills inside of a Biosafety Cabinet
    a. Stop work.
    b. If you are splashed by the material, change PPE. Always change gloves.
    c. Keep the biosafety cabinet running.
    d. Contain the spill by covering with paper towels (to avoid splashes or aerosols).
    e. Prepare the disinfectant.
    f. Saturate spill with XXXXXXX *(fill in the appropriate decontaminant).* Let sit for 20 minute exposure time.
        i. For large spills (greater than 10ml) use undiluted bleach or disinfectant.
        ii. In the event of a spill into the drip pan/catch basin, add an equal volume of disinfectant and wait for 20 minutes to clean up the disinfected material.
        iii. *Note: due to its evaporative nature alcohol is not recommended as the primary disinfectant but can be used to remove bleach/disinfectant residue.*
        iv. *If working with human blood or OPIM (such as human cell line) spills must be disinfected with an EPA-approved disinfectant (alcohol is not on the approved lists).*

g. Wipe up spill, disposing of towels in biohazard bag.
h. Spray spill area with XXXXXXX *(fill in the appropriate decontaminant).* Allow to air dry.
i. Disinfect all other materials used in the biosafety cabinet by disinfecting the surface with XXXXXXX *(fill in the appropriate decontaminant)* with a 20-minute contact time. Do not attempt to disinfect contaminated cardboard or other paper items that absorb liquid: contaminated items should be disposed of.
j. If bleach or other corrosive disinfectant used, wipe spill area and disinfected equipment with alcohol or water.
k. Place all towels or absorbent materials into a designated container for biohazardous waste.
l. Remove PPE, discard disposable PPE as biohazardous waste and wash hands.
m. Run the biosafety cabinet for 10 minutes to purge the air before re-starting work.

B. Spills outside of a Biosafety Cabinet
    a. Stop work.
    b. If you are splashed by the material, dispose of PPE and wash hands.
    c. Ensure that any other people in the vicinity are notified that a spill has occurred and that the room should be evacuated. Post a "Do Not Enter" notice on the door. Notify the PI or lab supervisor.
    d. If you need assistance with the spill clean-up, call EHS (1-6590).
    e. Wait 60 minutes before re-entering the room to allow aerosols to settle.
    f. Assemble Spill cleanup materials and don PPE, including lab coat, eye protection and face shield or mask, 2 pair of gloves, shoe covers. If the lab coat does not have cuffed sleeves, disposable sleeve covers should be worn.
    g. Contain the spill by covering with paper towels (to avoid splashes or aerosols)
    h. Saturate spill with XXXXXXX *(fill in the appropriate decontaminant).* Let sit for 20 minute exposure time.
        i. For large spills (greater than 10ml) use undiluted bleach or disinfectant.
        ii. Wipe areas around the spill that may have splatter and any reusable equipment with XXXXXXX *(fill in the appropriate decontaminant).*
        iii. *If working with human blood or OPIM (such as human cell line) spills must be disinfected with an EPA-approved disinfectant (alcohol is not on the approved lists).*
    i. Wipe up spill, disposing of towels in biohazard bag: if sharps may be present use tongs or a brush and pan and dispose in biohazard sharps container.
        i. Work concentrically to clean up the absorbent material. Always work from the outer edge of the spill toward the center.
    j. Spray spill area with XXXXXXX *(fill in the appropriate decontaminant).* Allow to air dry.
    k. If bleach or other corrosive disinfectant used, wipe spill area and disinfected equipment with alcohol or water.
    l. Remove PPE, discard disposable PPE as biohazardous waste and wash hands.
    m. Remove the "Do Not Enter" sign and inform others that it is safe to re-enter the room.

n. Once the spill has been contained, complete the "**SPILLS OR EXPOSURE EVENT REPORTING PROCEDURE"** form (below) and have the PI send to EHS.

C. Spills Inside of a Centrifuge Contained Within a Closed Cup, Bucket, or Rotor

a. Put on lab coat, gloves, and proper eye protection prior to opening centrifuge. Open carefully to assess the damage.
b. Prepare the disinfectant*: consult the instructions of the centrifuge rotor to identify suitable disinfectants*.
c. If the spill is contained within a closed cup, bucket, or rotor, spray the exterior with disinfectant and allow at least 20 minutes of contact time. Remove the carrier to the nearest biosafety cabinet (BSC).
    i. *Note, if possible, avoid using bleach on centrifuge rotors and buckets to avoid damaging the equipment. If bleach is used, ensure all surfaces are wiped down with soap and water after disinfection. Alternatively, use an EPA-registered disinfectant, such as Cidex or Cavicide.*
d. Gather supplies needed, such as a sharps container for broken glass and bins filled with disinfectant and place into the BSC.
e. Open the centrifuge rotor or bucket inside of the BSC. Use a mechanical device (forceps, tongs, etc.) to remove broken glass and place directly into sharps container. Carefully remove any unbroken tubes and place into a bin filled with XXXXXXX (*fill in the appropriate decontaminant*) for at least 20 minutes. Wipe carrier/bucket with disinfectant.
f. After disinfection, carrier, bucket, or rotor must be washed with a mild soap and water.
g. Spray the interior of the centrifuge chamber with XXXXXXX (*fill in the appropriate decontaminant*), let sit for at least 20 minutes and then wipe down with soap and water.
h. Dispose of all clean-up materials (except sharps) in an appropriate biohazardous waste container. Dispose of sharps in a biohazard sharps container.
i. Remove PPE, discard disposable PPE as biohazardous waste and wash hands.

If you are concerned that the spill is not contained within the rotor or bucket:

i. Ensure that any other people in the vicinity are notified that a spill has occurred and the room should be evacuated. Post a "Do Not Enter" notice on the door. Notify the PI or lab supervisor.
ii. If you need assistance with the spill clean-up, call EHS (801-581-6590)
iii. Wait 60 minutes before re-entering the room to allow aerosols to settle.
iv. Proceed with clean up as described above.

Note: Many centrifuge rotors can be disinfected by autoclaving. Check the manufacturer's instructions.

D. Exposure to skin or clothing

a. Stop work.
b. Take off contaminated clothing and wash affected area thoroughly with soap and water, but not so hard the skin is abraded.
c. If necessary, exit lab area and immediately take a shower. Wash thoroughly with soap and water, but not so hard the skin is abraded.
d. Notify the lab supervisor or PI.
e. If exposed to BSL-2/RG2 (or above) agent, notify the Biosafety Officer and Proceed directly to RedMed Clinic, Redwood Occupational Medicine Clinic, or the University of Utah Hospital Emergency Room (if after 8:30pm).

E. Penetrating wound
   a. Stop Work.
   b. Wash immediately with soap and water.
   c. Notify lab supervisor or PI, who must notify the Biosafety Officer.
   d. Proceed directly to RedMed Clinic, Redwood Occupational Medicine Clinic, or the University of Utah Hospital Emergency Room (if after 8:30pm).

F. Eyes, or mucous membrane exposure
   a. Stop work.
   b. Immediately flush eyes or mucous membrane with water for 10-15 minutes.
   c. Notify lab supervisor or PI, who must notify the Biosafety Officer.
   d. Proceed directly to RedMed Clinic, Redwood Occupational Medicine Clinic, or the University of Utah Hospital emergency Room (if after 8:30pm).

G. Emergency Spills: Environmental Risk
   a. Stop work.
   b. Ensure that any other people in the vicinity are notified that a spill has occurred and that the room should be evacuated. Post a “Do Not Enter” notice on the door. Notify the PI or lab supervisor.
   c. Call EHS (801-581-6590). Provide information on the nature of the material spilled.
   d. Take appropriate precautions to limit exposure or spread of spill to other areas.

NOTE: Spill Procedures must be clearly posted in the BSL-2 suite

Appendix C: Sharps Injury Log

A sharps injury log must be maintained by each supervisor for recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee. A new log should be created each calendar year.

Laboratory/Facility Name:_____ Year 2_____

Date	Case/ Report #	Type of Device (e.g. syringe, suture needle)	Brand Name of Device	Work Area where injury occurred (e.g. Geriatrics, Lab)	Brief description of how incident occurred (i.e., procedure being done, action being performed (disposal, injection, etc.), body part injured)

29 CRF 1910.1030, OSHA's Bloodborne Pathogens Standard, in paragraph (h)(5), requires an employer to establish and maintain a Sharps Injury Log for recording all percutaneous injuries in a facility occurring from contaminated sharps. The purpose of the Log is to aid in the evaluations of devices being used in healthcare and other facilities and to identify problem devices or procedures requiring additional attention or review. This log must be kept in addition to the injury and illness log required by 29 CFR 1904. The Sharps Injury Log should include all sharps injuries occurring in a calendar year. The Log must be retained for five years following the end of the year to which it relates. The Log must be kept in a manner that preserves the confidentiality of the affected employee.

Appendix D: Safer Sharps Annual Review Form

This form (or equivalent) must be completed on an annual basis by any University of Utah Facility/laboratory that performs sharps-related procedures on human samples or other potentially infectious material. Contact the Biosafety Office at (801) 581-6590 if you have questions or need further information.

Reviewer's Name: Job Title:

Department/Clinic: Date:

Supervisor/PI Name: Telephone #:

In accordance with OSHA's application of the "Needlestick Safety & Prevention Act", all sharps that are being used where there is exposure to human blood or OPIM must be reviewed on an annual basis. This includes all needles, syringes with needles, scalpels, capillary tubes, and lancets. During your annual review of devices, you must inquire about new or prospective safer options.

The purpose of this form is to document:

- Sharps devices currently in use;
- The criteria used in the selection of the safer sharps devices in use, and;
- Annual consideration of new safer sharps devices.

Complete the table below as completely as possible to document the sharps devices that are being used. Use multiple pages if necessary.

This review form must be maintained with your safety records.

	Device #1	Device #2	Device #3
Name of Sharps Device			
Manufacturer			
Model/Size in Use			
Procedures Performed			
***Safer Sharps Device? (Y/N)**			
Description of Safety Feature			
Justification for Selection (must consider newly marketed safer sharps devices			

*A justification must be documented (below) for any device that does **not** meet the criteria of a safer sharps device (see *Sharps with engineered sharps injury protection* definition below). Acceptable justifications include, but are not limited to:

- Use of a safer sharps device will jeopardize patient or employee safety.
- Use of a safer sharps device is medically inadvisable.
- Market unavailability of an appropriate safer sharps device.

Note that cost is not typically an acceptable justification.

Sharps with engineered sharps injury protection: This includes non-needle sharps or needle devices containing built-in safety features that are used for collecting fluids or administering medications or other fluids, or other procedures involving the risk of sharps injury. This description covers a broad array of devices, including:

- Syringes with a sliding sheath that shields the attached needle after use;
- Needles that retract into a syringe after use;
- Shielded or retracting catheters
- Intravenous medication (IV) delivery systems that use a catheter port with a needle housed in a protective covering.

Description of procedure and justification for not using safer sharps device:

Appendix E: Regulatory Matrix

The bloodborne pathogens compliance program responsibility matrix summarizes key provisions of the plan and correspond those responsibilities with the affected department or unit. The matrix should only be used as a quick reference.

Responsibility	Supervisors	EHS	Employee/ Student
Exposure Control Plan for Bloodborne Pathogens	Provide all affected personnel with access to the University of Utah and Facility-specific Exposure Control Plans.	Designate the Biological Safety Officer as the individual to oversee the University of Utah Exposure Control Plan. Develop, implement, and evaluate the Exposure Control Plan. Periodically update facility-specific Exposure Control Plan templates to ensure compliance with federal, state and local regulations.	Read, understand, and comply with the requirements of the Exposure Control Plans.
Exposure Determination	Identify and document personnel with potential exposure to bloodborne pathogens and the associated tasks and responsibilities of those positions and provide this information to EHS.	Assist departments with hazard assessments to determine jobs or tasks where exposure to bloodborne pathogens is possible.	Notify supervisor if job tasks and responsibilities present occupational exposure concerns that have not been previously identified. Alert others in the work area, before work begins, of activities that may expose themselves or others to bloodborne pathogens or OPIM.
Universal Precautions	Ensure that universal precautions are understood and executed by employees/students	Promote practices, procedures, and methods that conform to the concept of universal	Observe universal precautions when handling blood or OPIM.

Responsibility	Supervisors	EHS	Employee/ Student
	with possible exposure to bloodborne pathogens. Promote practices, procedures, and methods that conform to the concept of universal precautions.	precautions. Ensure that universal precautions are observed by employees/students with potential exposure to bloodborne pathogens.	
Engineering and Work Practice Controls	Design and implement engineering controls and institute work practice control procedures that will eliminate or minimize potential exposure to blood and OPIM	Provide guidance and technical assistance to departments in the design and selection of appropriate engineering and work practice controls.	Follow established work practice controls to eliminate of minimize occupational exposure. Be aware of engineering controls in the work place and the proper use of those controls.
Personal Protective Equipment	Provide appropriate personal protective equipment to personnel that have potential exposure to bloodborne pathogens.	Provide guidance and technical assistance to departments in the selection of the most appropriate types and quantities of personal protective equipment.	Be aware of the proper use, limitations, and location of available personal protective equipment. Use appropriate personal protective equipment to eliminate or minimize occupational exposure. Remove PPE when leaving the lab/facility.
Housekeeping	Maintain a clean and sanitary workplace environment. Develop and implement cleaning schedules as deemed appropriate for the types of activities and facilities involved.	Provide guidance and technical assistance to departments in the development and implementation of appropriate housekeeping methods.	Be aware of and observe established housekeeping procedures (e.g., use mechanical devices to clean up broken glass not bare hands). Maintain work area in a clean and sanitary manner.
HIV, HBV, and HCV Laboratories	Comply with additional criteria established for HIV, HBV or HCV	Provide guidance and technical assistance to laboratories engaged in	Understand the requirements and protection for personnel

Responsibility	Supervisors	EHS	Employee/ Student
	laboratories.	HIV, HBV, or HCV research.	working with HIV, HBV or HCV and follow established procedures.
Hepatitis B Vaccination	Ensure all employees with potential exposure to bloodborne pathogens enroll in the Hepatitis B vaccination program.	Assist departments in the identification of employees/students that have potential exposure to bloodborne pathogens. Provide information on how to enroll in the Hepatitis B virus vaccination program. Assist employees requesting vaccination.	Enroll in the Hepatitis B virus vaccination program in Open Range, administered by Occupational Medicine. If you request vaccination, complete the vaccination series on schedule and ensure your data are uploaded in Open Range upon completion of each dose and titer assessment.
Post Exposure Evaluation and Follow-up	Make available the hepatitis B vaccination to personnel identified through the process of exposure determination to have a potential exposure to bloodborne pathogens. Report exposure incidents to the Biological Safety Officer. Maintain needlestick logs and provide copies to EHS Biosafety upon request.	Provide direction on approved medical facilities capable of providing the confidential post exposure evaluation and follow-up. Ensure OSHA reporting requirements are met, if applicable.	Immediately seek treatment and as soon as feasible report all exposure incidents to your supervisors and EHS. Report all suspected exposure incidents.
Informing and Training	Coordinate and conduct facility-specific annual training required by the Exposure Control Plan. Contact EHS for instructions for how to register for bloodborne pathogen training provided by the University. Ensure	Create training opportunities as deemed necessary and appropriate for each affected department.	Attend initial and annual refresher biosafety and bloodborne pathogens training.

Responsibility	Supervisors	EHS	Employee/ Student
	employees receive training at the time of assignment and annually thereafter.		
Training Records	Compile and retain employee/student training records for a minimum of three years. Submit copies to EHS through SAM and provide documentation on request.	Review training records during lab inspections and IBC registrations.	
Labels and Signs	Affix appropriate labels to containers of regulated waste, refrigerators, freezers, and equipment containing blood or OPIM, and other containers of blood or OPIM. Post the universal biohazard symbol and appropriate Biological Safety Level at the entrance of HIV, HBV or HCV research laboratories.	Confirm that all equipment and containers are appropriately labeled during inspections.	Make certain that labels are appropriately affixed. Notify supervisor to report labeling problems.
Waste	Ensure waste is labeled and disposed properly.	Coordinate the proper management and disposal of regulated waste; disposal bags, containers, etc. must be obtained through SAM or procured by each department/facility.	Ensure waste is labeled and disposed properly.
Regulatory Compliance	Clearly identify the use of blood, products made from human blood, plasma, products made from plasma, or OPIM when registering or amending a	Assist departments in communicating the Exposure Control Plan to third-party vendors who perform tasks on campus that potentially implicate	Comply with all applicable requirements established in the OSHA Bloodborne Pathogens Standard and the University and Facility Exposure Control Plans.

Responsibility	Supervisors	EHS	Employee/ Student
	protocol with the IBC. Provide, at no cost, all supplies, and PPE, that are necessary for compliance with the Exposure Control Plan. Conduct periodic surveillance of activities within their respective areas to ensure compliance with the Exposure Control Plan. Comply with all applicable requirements established in the OSHA Bloodborne Pathogens Standard and the University Exposure Control Plan.	exposure control issues. Assist departments with Bloodborne Pathogens and exposure control issues upon request. Conduct periodic inspections to ensure compliance with the Exposure Control Plan. Serve as university liaison to regulatory authorities. Provide a means for suggestions, complaints, and concerns regarding the Exposure Control Plan.	Obtain or decline HBV vaccination.

Appendix F: Chemical Disinfection

In the laboratory setting, chemical disinfection is the most common method employed to decontaminate surfaces and disinfect waste liquids. In most laboratories, dilutions of household bleach is the preferred method but there are many alternatives that may be considered and could be more appropriate for some agents or situations. There are numerous commercially available products that have been approved by the Environmental Protection Agency (EPA). Many EPA-registered disinfectants have a 10-minute label claim. **However, EHS Biosafety recommends a 15-20 minute contact time for disinfection/decontamination.**

Prior to using a chemical disinfectant always consult the manufacturer's instructions to determine the efficacy of the disinfectant against the biohazards in your lab and be sure to allow for sufficient contact time. In addition, consult the Safety Data Sheet for information regarding hazards, the appropriate protective equipment for handling the disinfectant and disposal of disinfected treated materials. Federal law requires all applicable label instructions on EPA-registered products to be followed (e.g., use-dilution, shelf life, storage, material compatibility, safe use, and disposal). Do not attempt to use a chemical disinfectant for a purpose it was not designed for.

When choosing a disinfectant consider the following:

- The microorganisms present
- The item to be disinfected or surface(s)
- Corrosivity or hazards associated with the chemicals in the disinfectant
- Ease of use

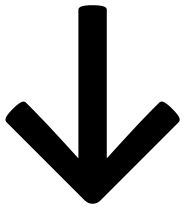
The OSHA Bloodborne Pathogen standard CFR 1910.1030 requires an EPA-registered disinfectant effective against HIV-1 and Hepatitis B virus. Therefore, diluted ethanol or isopropanol must not be used to disinfect materials and surface contaminated by human or non-human primate blood or other potentially infectious material (OPIM), as defined in the standard. However, alcohol-containing disinfectants, such as Cavicide and Opti-Cide Max, are registered by the EPA as virucidal and tuberculocidal.

1. Organism Sensitivity and Resistant Organisms

The innate characteristics of microorganisms often determine its sensitivity to chemical disinfection (**Table 1**). Some agents such as *Cryptosporidium*, *Clostridium difficile*, *Bacillus* spores and prions are very resistant to the usual disinfectants. EHS Biosafety is available to assist you in determining the appropriate disinfectant and provides guidance on use of appropriate disinfection techniques and

materials for researchers.

Table 1. Sensitivity of Microorganisms to Chemical Disinfectants

	Type of Microbe	Examples
More Resistant	Bacterial or Fungal Spores	*Bacillus subtilis, Clostridium difficile/perfringens, Cryptococcus*
.	Mycobacteria	*Mycobacterium tuberculosis, Mycobacterium bovis*
	Hydrophilic Viruses (non-enveloped)	Coxsackievirus, Rhinovirus, Adenovirus, Poliovirus
	Fungi	*Aspergillus., Candida sp.*
. .	Vegetative Bacteria	*Streptococcus pneumoniae, Staphylococcus aureus, E. coli, Pseudomonas spp., Klebsiella spp.*
Less Resistant	Lipophilic Viruses (lipid containing, enveloped)	Herpes Simplex virus, Cytomegalovirus, HIV (Lentiviruses)

2. Chemical Disinfectant Groups

a. Halogen-Based Biocides: (Chlorine Compounds and Iodophores)

i. Chlorine Compounds (e.g., Household Bleach)

Chlorine compounds are good disinfectants on clean surfaces, but are quickly inactivated by

organic matter, thus, reducing their biocidal activity. They have a broad spectrum of antimicrobial activity and are inexpensive and fast acting. Hypochlorites, the most widely used of the chlorine disinfectants, are available in liquid (e.g., Sodium hypochlorite), household bleach and solid (e.g., calcium hypochlorite, sodium dichloroisocyanurate) forms. Household bleach has an available chlorine content of 5.25%, or 52,500 ppm. For most purposes, **a 1:10 dilution of bleach** (approximately 0.5% or 5,000 ppm sodium hypochlorite) is recommended in the laboratory. Because of its oxidizing power, diluted bleach loses potency quickly and **should be made fresh** and used within a day or two of being prepared. **Bleach should be diluted with cold water in order to prevent breakdown of the disinfectant.** The free available chlorine levels of hypochlorite solutions in both opened and closed polyethylene containers are reduced to 40% to 50% of the original concentration over a period of one month at room temperature. Bleach should be stored between 50 and 70°F. According to Clorox, undiluted household bleach has a shelf life of six months to one year from the date of manufacture, after which it degrades at a rate of 20% each year until totally degraded to salt and water, and a **1:10 bleach solution has a shelf life of 24 hours**.

There are potential occupational exposure hazards when using hypochlorite solutions. The production of the carcinogen bis-chloromethyl ether when hypochlorite solutions come in contact with formaldehyde. The rapid production of chlorine gas when hypochlorite solutions are mixed with an acid. EHS has developed a Fact Sheet highlighting some of the risks of using bleach in the laboratory. Care must also be exercised in using chlorine–based disinfectants, which can corrode or damage metal, rubber, and other susceptible surfaces. Bleached articles should never be autoclaved without reducing the bleach with sodium thiosulfate or sodium bisulfate.

Chloramine T, which is prepared from sodium hypochlorite and p-toluenesulfonamide, is a more stable, odorless, less corrosive form of chlorine but has decreased biocidal activity in comparison to bleach.

ii. Iodophors (e.g. Betadyne)

Iodophors are used both as antiseptics and disinfectants, typically at a concentration of 25-1600 ppm of titratable iodine., Betadyne, Povidone-Iodine and other iodophors are commercially available Iodine-based disinfectants, which give good control when the manufacturer's instructions for formulation and application are followed. **Iodophors should be diluted in cold water in order to prevent breakdown of the disinfectant.**

An iodophor is a combination of iodine and a solubilizing agent or carrier; the resulting complex provides a sustained-release reservoir of iodine and releases small amounts of free iodine in aqueous solution. Antiseptic iodophors are not suitable for use as hard-surface disinfectants because they contain significantly less free iodine than do those formulated as disinfectants.

b. Alcohols (ethanol and isopropanol)

Alcohols work through the disruption of cellular membranes, solubilization of lipids, and denaturation of proteins by acting directly on S-H functional groups. Ethyl and isopropyl alcohols are the two most widely used alcohols for their biocidal activity. These alcohols are effective against lipid-containing viruses and a broad spectrum of bacterial species, but ineffective against spore-forming bacteria and many non-enveloped viruses. They evaporate rapidly, which makes extended contact times difficult to achieve unless the items are immersed.

The optimum bactericidal concentration for ethanol and isopropanol is in the range of 70% to 85% by volume. Their cidal activity drops sharply when diluted below 50% concentration. Absolute alcohol is also not very effective. They are used to clean sensitive equipment and are generally regarded as being non-corrosive.

Due to the evaporative nature of the solution, aqueous alcohol is not recommended as the primary disinfectant of spills, especially in areas with significant airflow, such as a Biosafety cabinet. For surface decontamination, a spray, wipe, spray approach is recommended to achieve the desired contact time.

c. Aldehydes: (Formaldehyde, Paraformaldehyde, Glutaraldehyde)

i. Glutaraldehyde:

Glutaraldehyde is a colorless liquid and has the sharp, pungent odor typical of all aldehydes, with an odor threshold of 0.04 parts per million (ppm). It is capable of sterilizing equipment, though to effect sterilization often requires many hours of exposure. Two percent solutions of glutaraldehyde exhibit very good activity against vegetative bacteria, spores and viruses. It is ten times more effective than formaldehyde and less toxic. However, it must be limited and controlled because of its toxic properties and hazards. It is important to avoid skin contact with glutaraldehyde as it has been documented to cause skin sensitization. Glutaraldehyde is also an inhalation hazard. The NIOSH ceiling threshold limit value is 0.2 ppm.

Cidex, a commercially prepared glutaraldehyde disinfectant is used routinely for cold surface sterilization of clinical instruments. Glutaraldehyde disinfectants must always be used in accordance with the manufacturer's directions.

ii. Formaldehyde:

Fomaldehyde and its polymerized solid paraformaldehyde have broad-spectrum biocidal activity and are both effective for surface and space decontamination. As a liquid (5% concentration), formaldehyde is an effective liquid decontaminant. Its biocidal action is through alkylation of carboxyl, hydroxyl and sulfhydryl groups on proteins and the ring nitrogen atoms of purine bases. Formaldehyde's drawbacks are reduction in efficacy at refrigeration temperature, its pungent, irritating odor, and several safety concerns. Formaldehyde is presently considered to be a carcinogen or a cancer-suspect agent according to several regulatory agencies. The OSHA 8-hour time-weighted exposure limit is 0.75 ppm.

d. Quaternary Ammonium Compounds: (Conflikt, Zephirin, CDQ, A-3)

Quaternary ammonium compounds are generally odorless, colorless, nonirritating, and deodorizing. They also have some detergent action, and they are good general-purpose disinfectants. However, some quaternary ammonium compounds activity is reduced in the presence of some soaps or soap residues, detergents, acids and heavy organic matter loads. They are generally ineffective against non-enveloped viruses, spores and *Mycobacterium tuberculosis*. They are typically diluted to 0.1 to 2%.

The mode of action of these compounds is through inactivation of energy producing enzymes, denaturation of essential cell proteins, and disruption of the cell membrane. Many of these compounds are better used in water baths, incubators, and other applications where halide or phenolic residues are not desired.

e. Phenolics: (O-phenophenoate-base Compounds)

Phenolics are phenol (carbolic acid) derivatives and typically used at 1- 5% dilutions. These biocides act through membrane damage and are effective against enveloped viruses, rickettsiae, fungi and vegetative bacteria. They also retain more activity in the presence of organic material than other disinfectants. Cresols, hexachlorophene, alkyl- and chloro derivatives and diphenyls are more active than phenol itself. Available commercial products include Lysol, Pine-Sol, Amphyl, O-Syl, Tergisyl, Vesphene, and LpH se.

Table 2. Summary and Comparison of Liquid Disinfectants

Class	Recommended Use	How They Work	Advantages	Disadvantages	Comments & Hazards	Examples
Chlorine Compounds	Spills of human body fluids Good against: Vegetative Bacteria Fungi Enveloped Viruses Non-enveloped Viruses Good at >1000ppm Sodium Hypochlorite: Spores Good with extended contact time: Mycobacteria	Free available chlorine combines with contents within microorganism, reaction byproducts cause its death Need 500 to 5000 ppm Produce chemical combination with cell substances Depends upon release of hypochlorous acid	Kills hardy viruses (e.g. hepatitis) Kills a wide range of organisms Inexpensive Penetrates well Relatively quick microbial kill May be used on food prep surfaces	Corrodes metals, such as stainless, aluminum Organics may reduce activity Increase in alkalinity decreases bactericidal property Unpleasant taste and odor Tuberculocidal, with extended contact time	Follow spill procedure and dilution instructions Make fresh solutions before use Eye, skin and respiratory irritant Corrosive Toxic	Bleach solutions (sodium hypochlorite) Clorox Cyosan Purex Clidox S
Iodophors (Iodine with carrier)	Disinfecting some semicritical medical equipment Very Good: Fungi Viruses Bacteria Some Spores Good with extended contact time: Mycobacteria	Free iodine enters microorganism and binds with cellular components Carrier helps penetrate soil/fat Probably by disorder of protein synthesis due to hindrance and/or blocking of hydrogen bonding	Kills broad range of organisms Highly reactive Low tissue toxicity Kills immediately rather than by prolonged period of stasis Not affected by hard water May be used on food prep surfaces	May stain plastics or corrode metal May stain skin/laundry Stains most materials Odor Some organic and inorganic substances neutralize effect Tuberculocidal, with extended contact time Sporicidal: Some	Dilution critical Follow directions! Use only EPA registered hard surface iodophor disinfectants Don't confuse skin antiseptic iodophors for disinfectants Skin and eye irritant Corrosive Toxic	Bactergent Hy-Sine Ioprep Providone (iodine/betadine)

Class	Recommended Use	How They Work	Advantages	Disadvantages	Comments & Hazards	Examples
Alcohols	Cleaning some instruments Cleaning skin	Changes protein structure of microorganism Presence of water assists with killing action	Fairly inexpensive	< 50% or >90% Solution not very effective Not active when organic matter present Not active against certain types of viruses Evaporates quickly Contact time may not be sufficient for killing	Flammable Eye Irritant Toxic	70% Ethanol Cavicide Opti-Cide Max
Glutaraldehyde	Good Against: Vegetative Bacteria Fungi Mycobacteria Viruses Spores	Coagulates cellular proteins	Non-staining, relatively noncorrosive Useable as a sterilant on plastics, rubber, lenses, stainless steel and other items that can't be autoclaved	Not stable in solution Has to be in alkaline solution Inactivated by organic material	Eye, skin and respiratory irritant Sensitizer Toxic	Cidex Calgocide 14 Vespore
Quaternary Ammonium compounds (QUATS)	Ordinary housekeeping (e.g. floors, furniture, walls) Good Against: Vegetative Bacteria Enveloped Viruses Fungi	Affects proteins and cell membrane of microorganism Releases nitrogen and phosphorous from cells	Contains a detergent to help loosen soil Rapid action Colorless, odorless Non-toxic, less corrosive Highly stable May be used on food prep surfaces	Does not eliminate spores, TB bacteria, some viruses Effectiveness influenced by hard water Layer of soap interferes with action	Select from EPA list of hospital disinfectants Skin and eye irritant Toxic	Conflikt Coverage 258 End-Bac Hi Tor Bacdown
Phenolic Compounds	Good Against:	Gross protoplasmic poison	Nonspecific concerning	Unpleasant odor	Skin and eye irritant	Hil-Phene

Class	Recommended Use	How They Work	Advantages	Disadvantages	Comments & Hazards	Examples
	Vegetative Bacteria Fungi Enveloped Viruses Some non-enveloped Viruses Mycobacteria	Disrupts cell walls Precipitates cell proteins Low concentrations inactivate essential enzyme systems	bactericidal and fungicidal action When boiling water would cause rusting, the presence of phenolic substances produces an anti-rusting effect	Some areas have disposal restrictions Effectiveness reduced by alkaline pH, natural soap or organic material Not Sporicidal	Sensitizer Corrosive Toxic	LpH se Metar Vesphene Decon-Cycle

3. Disposal

All liquid waste treated with chemical disinfectants must be disposed of as hazardous waste and collected for disposal by EHS, which can be arranged through the SAM System. The only exception is that waste treated with bleach may be poured down the drain, with running water.

Adapted from the University of Colorado and University of Virginia EHS websites.

Appendix G: SOP for Working in a Type II Biological Safety Cabinet

Type II Biological Safety Cabinets (BSCs) are available for use in many laboratories at the University of Utah. Any work or task with a potential for splash or aerosol generation with infectious materials requires the use of a BSC or other appropriate containment device. See the EHS Fact Sheets on "Biological Safety Cabinets" and "Biological Safety Cabinets: Selection, Installation and Maintenance". The following is an SOP that can be adapted for proper use of the BSC:

1. Turn on the blower in the cabinet at least 10 minutes before placing infectious materials into the hood.

2. Check the certification sticker and all biosafety cabinet monitors to verify that the biosafety cabinet is working properly. Biosafety cabinets must be certified prior to use. A qualified outside contractor must certify these cabinets annually. Check the certification sticker on the front of the unit to verify your biosafety cabinet's condition. If the re-certification date has passed contact EHS.

3. The biosafety cabinet air flow monitor should be checked to assure proper operation of the cabinet before placing any materials into it. Readings indicate relative pressure drop across the HEPA filter. Higher readings may, therefore, indicate filter clogging. Zero readings may indicate loss of filter integrity. In either of these cases, notify the Laboratory Manager or PI and EHS. University of Utah Facilities Management do not perform maintenance on biological safety cabinets. If the BSC needs to be serviced, contact EHS.

4. Gloves must be worn at all times.

5. Prior to beginning work, the BSC must be decontaminated. Don appropriate PPE (fluid resistant lab coat, gloves, eye protection). Clean the inside surfaces of the BSC with *(name of disinfectant)* and follow with water (if using bleach). DO NOT put head inside the cabinet. To reach the back of the cabinet use an extension, such as a Swiffer handle.

6. Let blower run for 10 min to filter the cabinet air of any particulates.

7. DO NOT disrupt the airflow through the hood by placing ANY item in front of or on the grills or by opening the door to the corridor. Disrupting the airflow into the front grill allows contaminated air from inside the cabinet to blow into the lab or directly at the person sitting at

the cabinet. It also allows non-sterile air from the room to blow into the biosafety cabinet over the experiments.

8. Organize the work surface for a clean-to-dirty work flow. Place clean pipets, flasks, and sterile media bottles at one side of the cabinet; place discard or kill pans containing disinfectant, biohazard waste containers, used flasks, spent cultures, and other wastes on the other side, with a work area in the center.

9. While working, keep all material and perform work at least 4 inches back from the front opening of the cabinet, and minimize rapid or movements or activity as well as sweeping motions with your arms.

10. In general, the interior of the hood should be considered to be a contaminated zone, even though every effort is made to keep the surfaces clean, as is consistent with accepted good microbiological practice and sterile technique.

11. After manipulating infectious agents, make sure all containers are tightly closed.

12. Plastic pipettes with a cotton plug shall be used for pipetting liquids containing viral particles. Electric pipettors shall be fitted with a 0.2 μm filter to prevent aerosol-based contamination.

13. A beaker or discard pan, containing a freshly prepared 1:10 solution of commercial bleach, shall be placed inside the biosafety cabinet during the cell culture work.

14. After pipetting liquid containing viral particles, the dilute bleach solution in the beaker shall be pipetted up and down the full length of the pipette or left in the pan.

15. After decontamination, pipette tips shall be removed from the pipettor and temporarily left in the beaker containing bleach in the biosafety cabinet.

16. Serological pipettes and tips should be placed in a in a puncture resistant sharps container or other approved receptacle inside the cabinet, or placed in a bath of disinfectant for at least 20 minutes prior to removal from the cabinet and transfer to a puncture resistant sharps container or other approved receptacle.

17. At the completion of the work, all materials will be removed from the biosafety cabinet: all items must be decontaminated prior to removal. *Describe methods for decontamination.*

18. At the completion of the work, the beaker containing the plastic tip pipettes shall be removed from the biosafety cabinet. Pipettes tips shall be lifted out of the beaker, the bleach solution allowed to drain back into the beaker, and the pipette tips placed in a puncture resistant sharps container or other approved receptacle. NOTE plastic pipette tips and serological pipettes are treated as sharps.

19. Small volumes of liquid waste containing viral particles shall be collected in a beaker containing undiluted bleach inside the biosafety cabinet. The final concentration of bleach should be at least 10% of the final volume. After completing work, wait at least 30 minutes before disposing down the drain.

20. Large volumes should be collected by vacuum aspiration into a flask containing an appropriate disinfectant, such as Vesphene III se or bleach, up to 1 or 10% of the volume of the flask, respectively. **NOTE: No untreated or non-disinfected biological agent-containing material should be allowed into any drain connected to the sanitary sewer system (e.g., from a sink).**

    i. Bleach in the vacuum traps must be changed at least twice per week or when the flask is half full, whichever is sooner. Wait at least 20 minutes after finishing work to discard waste.

    ii. For ZZZ or Vesphene III Se, change at least every 3 months (indicate the date of the last change on the flask). Ensure the media is exposed to disinfectant for at least 20 minutes prior to disposal. Collect waste into containers marked “Unwanted Materials” and date when you start collecting. When full or 6 months after your start date (whichever happens first), arrange pickup by EHS through the SAM website. **NO DRAIN DISPOSAL without EHS approval.**

    iii. *The flask should be placed in a secondary container to prevent it from tipping over, be labeled with a biohazard sticker and the vacuum line must be protected by a hydrophobic (HEPA) filter. The vacuum filters must be replaced if clogged or if liquid makes contact with the filter. Examples include Whatman Vacu-guard and Pall Gelman Vacushield in-line disk filters. Used filters should be placed in the biohazard waste.*

1. Turn off the house vacuum when not in use.

2. Clean the inside surfaces of the BSC with *(name of disinfectant)* after completion of work, and follow with water (if using bleach).

3. Allow the blower to run for at least 10 minutes following use.

Note: **EHS strongly discourages the use of Ultraviolet (UV) lamps in Biological Safety Cabinets (BSCs): see EHS Fact Sheet.** If a UV lamp is used, follow the procedures below.

- UV lights must be turned off whenever the room is occupied.
- Post a warning sign on the front of the BSC indicating the presence of UV light hazards.
  - The sign must say CAUTION: Turn off UV light before working.
- Turn the UV light off after 15 minutes. If UV lights will be used overnight or for extended periods of time while staff are not present, the sign should be posted on the outside of the closed door of the room.
- For biological safety cabinets with sashes that close, the light must only be used when the sash is fully closed. Sash alarms or mechanisms ensuring this feature may not be disabled.
- All items to be removed from the BSC and surfaces of the BSC must be decontaminated prior to UV light use.

  UV light is effective only for decontaminating clean, solid surfaces with which it comes in contact. It is not effective in decontaminating the cabinet air flow. UV light is not effective against bacterial spores. UV germicidal light tubes should be replaced frequently (at least every 6 months for biosafety cabinets in use on a daily basis) to assure that they are emitting light at 254 nm and at an intensity appropriate for decontamination. ***Due to concerns over the effectiveness of these lights and the health risks to individuals in the room, some Institutions, such as the NIH, have banned their use in BSCs.***

NOTE: Open Flames (Bunsen Burners) are not allowed to be used in BSCs at the University of Utah: See EHS Fact Sheet.

NOTE: Any use of volatile solvents, such as absolute ethanol, must be kept to a minimum or done elsewhere. **Dangerously high levels of volatile vapors can accumulate inside the cabinet and pose a threat of fire or explosion.**

NOTE: *Be very careful when using small pieces of materials in the BSC as they can be blown into the grills and disrupt the motor operations.*

Annual certification of the BSC confirms that it will provide the user and experimental material the

protection for which it is designed. The airflow, filters, and cabinet integrity are checked to ensure that the cabinet meets minimum performance standards. Certification and decontamination are arranged through EHS and provided by an outside vendor. A sticker on the BSC will list when certification is due. If certification is past due, please contact EHS.

BSCs intended for research with biohazardous materials must be certified:

- After they are received and installed (before use with infectious materials).
- After filter changes.
- After being moved (even a few feet).
- Annually.
- By an NSF-certified technician.

BSC decontamination (e.g., using a peroxide gas process) must be provided and needs to be done:

- Before any maintenance work requiring disassembly of the air plenum, including filter replacement.
- Prior to cabinet recertification.
- Before moving the cabinet to a new laboratory.
- Before discarding or salvaging.
- By an NSF-certified technician.

Note: all maintenance work inside of the biosafety cabinet must be performed by an NSF-certified technician. Work on the exterior of the cabinet, such as connecting vacuum or gas lines can be performed by University of Utah Facilities. Please contact EHS (801-581-6590) prior to having any work performed on the BSC.

Biosafety Cabinet malfunction

<u>Signs of Biological Safety Cabinet Failure</u>

If any of the following signs of biological safety cabinet failure are observed work should be stopped as quickly and safely as possible.

1. Power failure – lights within the cabinet will go out and the blower motor will stop. Laminar flow within the cabinet has failed.
2. No airflow – if you can't feel the downward airflow in the cabinet the air curtain has failed.

3. Alarm sounding or visible on cabinet – modern biological safety cabinets are commonly equipped with audible or visual alarm systems which warn the operator when the cabinet malfunctions.
4. Unusual noises – if unusual noises such as squeaking, squealing, loud humming, knocking, or buzzing occur they could indicate failure or imminent failure of the cabinet's mechanical and/or control systems.
5. Unusual smells – unusual smells such as ozone or smoke could indicate a fire within the cabinet.

Response Procedure

Personal Safety is more important than the integrity of the experiment

If any of the signs of cabinet failure described above are observed when starting or attempting to start the biological safety cabinet **do not start work**. If any of the signs of cabinet failure described above are observed while work is occurring in the cabinet, follow the steps below.

1. Stop working immediately. If safe to do so follow steps 2-14. If conditions are immediately dangerous to life and health evacuate.
2. Move slowly and smoothly to prevent aerosols from spreading.
3. Cap, cover or otherwise package any vessels that contain biological agents.
- If you are working with animals ensure that the cage is closed and leave within the cabinet.
4. Back out of the biological safety cabinet and close the sash (if it closes)
5. Remove and discard your gloves as biohazardous waste.
6. Switch off the alarm and blower motor.
7. Advise other workers in the area of the cabinet failure.
8. Post a warning sign on the sash of the cabinet (have a copy in the room ready for emergencies).
9. Wash hands and vacate the room, waiting at least 30 minutes for aerosols to settle before re-entering the room.

- If the failure is due to BSC malfunction: keep the sash closed until power returns. The contents must be decontaminated and removed and the surface decontaminated before it can be serviced. Ensure that the BSC is decontaminated before any internal repairs are carried out. Contact EHS Biosafety at (801) 581-6590 or Biosafety@EHS.Utah.edu for advice on how to proceed.
- If the malfunction is due to a power outage, once the power has returned and at least 30 minutes have passed, the cabinet may be used but all contents must be appropriately surface decontaminated prior to the resumption of work.
- If an aerosol transmissible pathogen was being used and you are concerned that there could be contamination of the room contact EHS Biosafety at (801) 581-6590 or Biosafety@EHS.Utah.edu.

10. Don the appropriate personal protective equipment (gloves, lab coat or back fastening gown, safety glasses).
    - If an aerosol transmissible agent was used and you are concerned that there could be contamination of the room or if the disruption was due to the cabinet failure, contact EHS Biosafety at (801) 581-6590 or Biosafety@EHS.Utah.edu.
11. Open the sash of the cabinet slowly and carefully to prevent aerosols from spreading.
12. If the failure was due to a power loss then restart the cabinet and wait at least 15 minutes.
13. Package and decontaminate in order – tools/equipment, sample containers, waste and the cabinet working surface and interior.
14. To ensure that appropriate medical follow-up action is taken, notify your supervisor if anyone may have been exposed to infectious material due to the cabinet failure and submit a Hazard/Incident Report to EHS (https://oehs.utah.edu/incidentnear-miss-report).

Reference: *Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets, See Appendix A. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, and National Institutes of Health.*

Appendix H: Model SOP for Handling Human Materials Containing Pathogens or Conducting Procedures that Create Aerosols

Handling Human Tissues and Cells

This SOP applies to individuals who work with human materials, including cells, blood, serum, tissues, feces and body fluids, where aerosols may be generated or samples are known to contain pathogens.

Individuals working with human materials have an increased risk for exposure to bloodborne pathogens, such as Hepatitis B virus, Hepatitis C virus or Human Immunodeficiency virus. The OSHA Bloodborne Pathogens standard (CFR 1910.1030) describes the requirement for working with these cells, including engineering and work practice controls and PPE.

Personal Protective Equipment

Engineering Controls, Equipment, and Materials

Biosafety Cabinet (BSC)	Enclosed, ventilated laboratory workspace that protects the worker from aerosols
Biohazard Waste Container(s)	Solid, sharps and/or liquid waste containers, as appropriate, compliant with medical waste handling requirements
Disinfectant	Appropriate for human tissues and cells
Splash Shield	Plexiglas or other shield that separates open containers of hazardous materials from the user and behind which work can be conducted

Procedures

1. Don and doff PPE appropriate for procedures involving human materials (e.g., safety goggles required when splashing is anticipated)
2. Conduct all work in a Biosafety Cabinet.
3. Decontaminate instruments, equipment and work surfaces that have come into contact with human materials with an appropriate EPA-registered disinfectant
4. Dispose of items that have come into contact with human materials as biohazardous waste
5. Dispose of sharps (e.g., needles, scalpels, syringes) as biohazardous sharps waste
6. Wash hands with soap and water immediately after glove removal

Cautions and Considerations

- All work must be registered with and approved by the institutional Biosafety Committee, including an emergency response plan for exposures
- The laboratory must have a facility-specific Biosafety Manual or Exposure Control Plan
- Bloodborne Pathogens training must be conducted on an annual basis: contact EHS Biosafety
- Consult with EHS Biosafety if it is unclear whether a procedure creates aerosols
- Additional PPE (e.g., double gloves) may be required for certain procedures
- Reduce or eliminate sharps and glass (consult with EHS Biosafety for safer alternatives)
- Follow post-exposure procedures for an exposure and contact EHS at 801-581-6590 within 12 hours

Appendix I: Model SOP for Handling Human Materials Outside of a Biosafety Cabinet

Handling Human Materials Outside of a Biosafety Cabinet

This SOP applies to splash- or spray-generating procedures with human materials conducted outside of a biosafety cabinet (BSC). This SOP **does not apply** to working with samples known to be positive for human pathogens or obtained from infected individuals.

Although an aerosol containment device (e.g., BSC) is preferred, it is not required for procedures with human materials that DO NOT create aerosols. However, a BSC must be used to provide protection from potentially infectious aerosols generated by procedures, such as vortex mixing, sonication, homogenizing, grinding, and blending. In the absence of an aerosol containment device, splash or spray protection is needed for the worker.

Personal Protective Equipment


Lab Coat


Gloves


Safety Glasses

Engineering Controls, Equipment, and Materials

Biosafety Cabinet (BSC)	Enclosed, ventilated laboratory workspace that protects the worker from aerosols
Biohazard Waste Container(s)	Solid, sharps and/or liquid waste containers, as appropriate, compliant with medical waste handling requirements
Disinfectant	EPA-Registered Disinfectant
Splash Shield	Plexiglas or other shield that separates open containers of hazardous materials from the user and behind which work can be conducted

Procedures

1. Don and doff PPE appropriate for procedures involving human materials
2. Conduct all work with open containers behind a splash shield
3. Perform procedures that could create aerosols within a BSC (e.g., cell culture, tissue harvest, centrifugation, sonication, vortexing, homogenizing, etc.)
4. Decontaminate instruments, equipment and work surfaces that have come into contact with human materials with an EPA-registered disinfectant
5. Dispose of items that have come into contact with human materials as biohazardous waste
6. Dispose of sharps (e.g., needles, scalpels, syringes) as biohazardous sharps waste
7. Wash hands with soap and water immediately after glove removal

Cautions and Considerations

1. All work must be registered with and approved by the Institutional Biosafety Committee, including an emergency response plan for exposures
2. If samples are known to contain airborne-transmissible pathogens, work must be conducted in a biosafety cabinet
3. The laboratory must have a facility-specific Biosafety Manual or Exposure Control Plan
4. Bloodborne Pathogens training must be conducted on an annual basis: contact EHS Biosafety
5. A face shield or surgical mask (in addition to safety glasses) can be used in place of the splash shield
6. Consult with EHS Biosafety if it is unclear whether a procedure creates aerosols
7. Additional PPE (e.g., double gloves) may be required for certain procedures
8. Reduce or eliminate sharps and glass (consult with EHS Biosafety for safer alternatives)
9. Follow post-exposure procedures for an exposure and contact EHS at 801-581-6590 within 12 hours

Appendix J: Model SOP for Decontamination and Disinfection

Decontamination and Disinfection

This SOP applies to individuals who handle, manipulate, transfer, store or dispose of biohazardous agents. This SOP is intended to complement the liquid biohazardous waste SOP.

Biological agents can pose varying risks of harm to humans, animals and the environment, including life-threatening disease and chronic illnesses. Therefore, appropriate decontamination of equipment and waste is critical to prevent contact with and release of harmful biological agents.

Personal Protective Equipment

BSL1 or BSL2

BSL2+

Engineering Controls, Equipment, and Materials

Chemical Disinfectant	A disinfectant that has been validated to deactivate the biological agent of interest. For blood or other potentially infectious material, use an EPA-registered disinfectant
Disposable Absorbent Material	A material that can absorb liquids and can be disposed as hazardous waste (e.g., paper towels)

Procedures

1. Don appropriate PPE for the live biological agent and the chemical disinfectant
2. If necessary, dilute/reconstitute chemical disinfectant to the concentration required to deactivate the agent, making sure to factor in the volume of liquid waste

3. Disinfect the interior and exterior of the safety cup/rotor following the Decontamination SOP

For Liquids

3. Carefully pour disinfectant into liquid waste so that the final concentration of the disinfectant deactivates the agent
4. Wait the contact time required to deactivate the agent (at least 20 minutes)
5. Dispose of decontaminated liquid waste as chemical hazardous waste

NOTE: *Liquid solutions containing bleach and no other chemicals may be disposed down the drain with copious amounts of water. Other liquids must be disposed of as hazardous chemical waste (use the EHS SAM to arrange for collection)*

For Solids

3. Apply disinfectant to the contaminated surface so that it is saturated
4. Keep the surface saturated for the contact time

   required to deactivate the agent
5. Wipe up chemical disinfectant from saturated area with absorbent materials
6. Dispose of absorbent materials following the SDS recommendations for the disinfectant

Cautions and Considerations

- The disinfectant in use, the active concentration and the required contact time must be defined in the laboratory Biosafety Manual and/or Exposure Control Plan, and approved by the Institutional Biosafety Committee
- Additional PPE may be required to handle the agent and/or the chemical disinfectant
- An appropriate disinfectant that can deactivate your agent is required and varies from agent to agent
- Ensure that the chemical disinfectant used is chemically compatible with any solutions it is mixed in

References

1. Lists of EPA-registered Disinfectants
2. EHS Chemical Disinfection Fact Sheet

3. Public Health Agency of Canada Pathogen Safety Data Sheets
4. EHS Fact Sheet on Sodium Hypochlorite compatibility

Appendix K: Injection of Human Cells or Tissues into Animals

The potential hazards associated with the handling of human/nonhuman primate cell culture are mainly the contamination of the cells with pathogenic agents and/or the tumorigenicity of the cells. Agents such as bacteria, fungi, and mycoplasmas generally cause some kind of visual effect on the cells or culture media allowing for detection of contamination. However, many viruses do not cause cytopathic effect (CPE), can be latent or are undetectable with current technology.

Primate and other mammalian cell lines can harbor viruses with a broad host range. Human cell lines are most likely to be contaminated with the highly pathogenic viruses including hepatitis B virus and HIV (human immunodeficiency virus). It must be understood though, that Primate cells can contain dangerous pathogens, most notably herpes B virus and Marburg virus both of which have caused fatal infections in humans. Rodent cell lines can carry lymphocytic choriomeningitis virus (LCMV), Reo-3 virus and hantavirus with documented cases of human disease and death.

In 1994, OSHA issued an interpretation of the applicability of the Bloodborne Pathogen (BBP) Standard towards human cell lines. According to the interpretation, human cell lines are considered to be potentially infectious and within the scope of the BBP Standard unless the specific cell line has been characterized to be free of recognized bloodborne pathogens. The American Type Culture Collection (ATCC) recommends that all human cell lines be accorded the same level of biosafety consideration as a line known to human risk group 2 pathogens (BSL-2) unless they have been screened for human pathogens.

In addition, the 6th Edition of the NIH/CDC publication, *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) recommends that human and other primate cells should be handled using Biosafety Level-2 (BSL-2) practices and containment.

Based on these recommendations, the University of Utah Institutional Biosafety Committee and Attending Veterinarian (AV) requires Animal Biosafety level 2 (ABSL-2) practices to be followed when animals are injected/implanted with human cell lines (primary or established), human tissues or human tumors. This work must be registered with the IBC through BioRAFT.

If a PI wishes to use lower containment (ABSL-1), the PI must submit a request to the IBC as part of their registration in BioRAFT. The IBC Chair, and/or Biosafety Officer (BSO) will review the application, with review by the full IBC if deemed appropriate by the Chair or BSO.

Biologics that require testing for human pathogens (see below) with review and approval by the IBC

prior to in vivo rodent use at ABSL-1:

a. Human-derived cell lines, transplantable tumors, serum, tissues, body fluids, and antibody preparations that have not been passed through rodents or have not been exposed to rodents.

Possible exemptions from testing requirements, but not from review and approval by the AV and/or by the IBC:

a. Commercially obtained biological material for which the vendor (e.g. ATCC[+]) can supply negative screening results for murine and/or human pathogens on UofU's exclusion lists.
b. If ABSL-2 practices will be followed when using human-derived biological material in rodents.

Pathogen Testing: Recommended Testing Laboratories

a. Charles River Laboratories http://www.criver.com/products-services/basic-research/health-monitoring-diagnostic-services/cell-line-research-biologics-screening
    i. Human Infectious Agent Panels
        1. U Utah IBC Human Biologics CLEAR Panel (9 Agent Human CLEAR)
        2. Human HEP/HIV panel plus LCMV and HTLV*
b. IDEXX BioResearch https://www.idexxbioanalytics.com/hubfs/IBA_Q1_2022_NA_DOS.pdf
    i. h-IMPACT 1 (Human Pathogen) Testing panel
    ii. h-IMPACT 3 (Human Pathogen) Testing panel plus LCMV and *Corynebacterium bovis*[#]

c. Other laboratories may be used, but must be pre-approved by the AV and/or by the IBC.

Copies of the biologics testing results should be retained and accessible (uploaded in the EHS Safety Administrative Management (SAM) System).

Notes:

+ As of January 2010, all human cell lines accessioned in the ATCC general collection are tested for the adventitious agents HIV, HBV, HCV, HPV, EBV, and CMV. As of August 2012, the Hepatitis C test was removed from the ATCC virus panel test. Testing for *Corynebacterium bovis* is evaluated through their

routine sterility testing for bacteria (using a BacT/ALERT 3D system), which is done on each lot. All cell lines must be mycoplasma free when deposited but ATCC recommend periodic testing when being cultured: they sell mycoplasma testing kits and services.

*Established human cell lines without testing for LCMV or HCV will be considered by the IBC on a case by case basis. LCMV typically causes lytic infections of human cells while no cell lines supporting HCV replication have been identified to date.

#Human samples obtained from patients are unlikely to harbor *Corynebacterium bovis* and an exemption to testing will be considered by the IBC.

In addition, the University of Utah AV has requirement for testing of cell lines for animal pathogens prior to injection into animals at ABSL-1, such as testing for murine materials.

List of Agents Excluded from University of Utah Human Biologics^

1. Human Immunodeficiency Virus Type 1 and 2 (HIV)
2. Hepatitis A Virus (HAV)
3. Hepatitis B Virus (HBV)
4. Hepatitis C Virus (HCV)
5. Human T-lymphotropic Virus (HTLV)
6. Lymphocytic Choriomeningitis Virus (LCMV)
7. *Mycoplasma spp.*
8. *Corynebacterium bovis*

^Testing for additional agents may be required based on the source of the material. These will be determined by the IBC.

Appendix L: OSHA Bloodborne Pathogen Standard

1910.1030(a)

Scope and Application. This section applies to all occupational exposure to blood or OPIM as defined by paragraph (b) of this section.

1910.1030(b)

Definitions. For purposes of this section, the following shall apply:

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, or designated representative.

Blood means human blood, human blood components, and products made from human blood.

Bloodborne Pathogens means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

Clinical Laboratory means a workplace where diagnostic or other screening procedures are performed on blood or OPIM.

Contaminated means the presence or the reasonably anticipated presence of blood or OPIM on an item or surface.

Contaminated Laundry means laundry which has been soiled with blood or OPIM or may contain sharps.

Contaminated Sharps means any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.

Decontamination means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

Director means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designated representative.

Engineering Controls means controls (e.g., sharps disposal containers, self-sheathing needles, safer medical devices, such as sharps with engineered sharps injury protections and needleless systems) that isolate or remove the bloodborne pathogens hazard from the workplace.

Exposure Incident means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or OPIM that results from the performance of an employee's duties.

Handwashing Facilities means a facility providing an adequate supply of running potable water, soap, and single-use towels or air-drying machines.

Licensed Healthcare Professional is a person whose legally permitted scope of practice allows him or her to independently perform the activities required by paragraph (f) Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up.

HBV means hepatitis B virus.

HIV means human immunodeficiency virus.

Needleless systems means a device that does not use needles for:

(1) The collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established; (2) The administration of medication or fluids; or (3) Any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

Occupational Exposure means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or OPIM that may result from the performance of an employee's duties.

OPIM means (1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any 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; (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

Parenteral means piercing mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, and abrasions.

Personal Protective Equipment is specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as

protection against a hazard are not considered to be personal protective equipment.

Production Facility means a facility engaged in industrial-scale, large-volume or high concentration production of HIV or HBV.

Regulated Waste means liquid or semi-liquid blood or OPIM; contaminated items that would release blood or OPIM in a liquid or semi-liquid state if compressed; items that are caked with dried blood or OPIM and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or OPIM.

Research Laboratory means a laboratory producing or using research-laboratory-scale amounts of HIV or HBV. Research laboratories may produce high concentrations of HIV or HBV but not in the volume found in production facilities.

Sharps with engineered sharps injury protections means a non-needle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.

Source Individual means any individual, living or dead, whose blood or OPIM may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinic patients; clients in institutions for the developmentally disabled; trauma victims; clients of drug and alcohol treatment facilities; residents of hospices and nursing homes; human remains; and individuals who donate or sell blood or blood components.

Sterilize means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.

Universal Precautions is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.

Work Practice Controls means controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).

1910.1030(c)

Exposure Control --

1910.1030(c)(1)

Exposure Control Plan.

1910.1030(c)(1)(i)

Each employer having an employee(s) with occupational exposure as defined by paragraph (b) of this section shall establish a written Exposure Control Plan designed to eliminate or minimize employee exposure.

1910.1030(c)(1)(ii)

The Exposure Control Plan shall contain at least the following elements:

1910.1030(c)(1)(ii)(A)

The exposure determination required by paragraph (c)(2),

1910.1030(c)(1)(ii)(B)

The schedule and method of implementation for paragraphs (d) Methods of Compliance, (e) HIV and HBV Research Laboratories and Production Facilities,
(f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, (g) Communication of Hazards to Employees, and (h) Recordkeeping, of this standard, and

1910.1030(c)(1)(ii)(C)

The procedure for the evaluation of circumstances surrounding exposure incidents as required by paragraph (f)(3)(i) of this standard.

1910.1030(c)(1)(iii)

Each employer shall ensure that a copy of the Exposure Control Plan is accessible to employees in accordance with 29 CFR 1910.1020(e).

1910.1030(c)(1)(iv)

The Exposure Control Plan shall be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure. The review and update of such plans shall also:

1910.1030(c)(1)(iv)(A)

Reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens; and

1910.1030(c)(1)(iv)(B)

Document annually consideration and implementation of appropriate commercially available and effective

safer medical devices designed to eliminate or minimize occupational exposure.

1910.1030(c)(1)(v)

An employer, who is required to establish an Exposure Control Plan shall solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the Exposure Control Plan.

1910.1030(c)(1)(vi)

The Exposure Control Plan shall be made available to the Assistant Secretary and the Director upon request for examination and copying.

1910.1030(c)(2)

Exposure Determination.

1910.1030(c)(2)(i)

Each employer who has an employee(s) with occupational exposure as defined by paragraph (b) of this section shall prepare an exposure determination. This exposure determination shall contain the following:

1910.1030(c)(2)(i)(A)

A list of all job classifications in which all employees in those job classifications have occupational exposure;

1910.1030(c)(2)(i)(B)

A list of job classifications in which some employees have occupational exposure, and

1910.1030(c)(2)(i)(C)

A list of all tasks and procedures or groups of closely related task and procedures in which occupational exposure occurs and that are performed by employees in job classifications listed in accordance with the provisions of paragraph (c)(2)(i)(B) of this standard.

1910.1030(c)(2)(ii)

This exposure determination shall be made without regard to the use of personal protective equipment.

1910.1030(d)

Methods of Compliance --

1910.1030(d)(1)

General. Universal precautions shall be observed to prevent contact with blood or OPIM. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids shall be considered potentially infectious materials.

1910.1030(d)(2)

Engineering and Work Practice Controls.

1910.1030(d)(2)(i)

Engineering and work practice controls shall be used to eliminate or minimize employee exposure. Where occupational exposure remains after institution of these controls, personal protective equipment shall also be used.

1910.1030(d)(2)(ii)

Engineering controls shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness.

1910.1030(d)(2)(iii)

Employers shall provide handwashing facilities which are readily accessible to employees.

1910.1030(d)(2)(iv)

When provision of handwashing facilities is not feasible, the employer shall provide either an appropriate antiseptic hand cleanser in conjunction with clean cloth
/ paper towels or antiseptic towelettes. When antiseptic hand cleansers or towelettes are used, hands shall be washed with soap and running water as soon as feasible.

1910.1030(d)(2)(v)

Employers shall ensure that employees wash their hands immediately or as soon as feasible after removal of gloves or other personal protective equipment.

1910.1030(d)(2)(vi)

Employers shall ensure that employees wash hands and any other skin with soap and water, or flush mucous membranes with water immediately or as soon as feasible following contact of such body areas with blood or OPIM.

1910.1030(d)(2)(vii)

Contaminated needles and other contaminated sharps shall not be bent, recapped, or removed except as noted in paragraphs (d)(2)(vii)(A) and (d)(2)(vii)(B)

below. Shearing or breaking of contaminated needles is prohibited.

1910.1030(d)(2)(vii)(A)

Contaminated needles and other contaminated sharps shall not be bent, recapped or removed unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure.

1910.1030(d)(2)(vii)(B)

Such bending, recapping or needle removal must be accomplished through the use of a mechanical device or a one-handed technique.

1910.1030(d)(2)(viii)

Immediately or as soon as possible after use, contaminated reusable sharps shall be placed in appropriate containers until properly reprocessed. These containers shall be:

1910.1030(d)(2)(viii)(A)

Puncture resistant;

1910.1030(d)(2)(viii)(B)

Labeled or color-coded in accordance with this standard;

1910.1030(d)(2)(viii)(C)

Leakproof on the sides and bottom; and

1910.1030(d)(2)(viii)(D)

In accordance with the requirements set forth in paragraph (d)(4)(ii)(E) for reusable sharps.

1910.1030(d)(2)(ix)

Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure.

1910.1030(d)(2)(x)

Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets or on countertops or benchtops where blood or OPIM are present.

1910.1030(d)(2)(xi)

All procedures involving blood or OPIM shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances.

1910.1030(d)(2)(xii)

Mouth pipetting / suctioning of blood or OPIM is prohibited.

1910.1030(d)(2)(xiii)

Specimens of blood or OPIM shall be placed in a container which prevents leakage during collection, handling, processing, storage, transport, or shipping.

1910.1030(d)(2)(xiii)(A)

The container for storage, transport, or shipping shall be labeled or color-coded according to paragraph (g)(1)(i) and closed prior to being stored, transported, or shipped. When a facility utilizes Universal Precautions in the handling of all specimens, the labeling / color-coding of specimens is not necessary provided containers are recognizable as containing specimens. This exemption only applies while such specimens / containers remain within the facility. Labeling or color- coding in accordance with paragraph (g)(1)(i) is required when such specimens / containers leave the facility.

1910.1030(d)(2)(xiii)(B)

If outside contamination of the primary container occurs, the primary container shall be placed within a second container which prevents leakage during handling, processing, storage, transport, or shipping and is labeled or color-coded according to the requirements of this standard.

1910.1030(d)(2)(xiii)(C)

If the specimen could puncture the primary container, the primary container shall be placed within a secondary container which is puncture-resistant in addition to the above characteristics.

1910.1030(d)(2)(xiv)

Equipment which may become contaminated with blood or OPIM shall be examined prior to servicing or shipping and shall be decontaminated as necessary, unless the employer can demonstrate that decontamination of such equipment or portions of such equipment is not feasible.

1910.1030(d)(2)(xiv)(A)

A readily observable label in accordance with paragraph (g)(1)(i)(H) shall be attached to the equipment stating which portions remain contaminated.

1910.1030(d)(2)(xiv)(B)

The employer shall ensure that this information is conveyed to all affected employees, the servicing representative, and / or the manufacturer, as appropriate, prior to handling, servicing, or shipping so that appropriate precautions will be taken.

1910.1030(d)(3)

Personal Protective Equipment --

1910.1030(d)(3)(i)

Provision. When there is occupational exposure, the employer shall provide, at no cost to the employee, appropriate personal protective equipment such as, but not limited to, gloves, gowns, laboratory coats, face shields or masks and eye protection, and mouthpieces, resuscitation bags, pocket masks, or other ventilation devices. Personal protective equipment will be considered "appropriate" only if it does not permit blood or OPIM to pass through to or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used.

1910.1030(d)(3)(ii)

Use. The employer shall ensure that the employee uses appropriate personal protective equipment unless the employer shows that the employee temporarily and briefly declined to use personal protective equipment when, under rare and extraordinary circumstances, it was the employee's professional judgment that in the specific instance its use would have prevented the delivery of health care or public safety services or would have posed an increased hazard to the safety of the worker or co-worker. When the employee makes this judgment, the circumstances shall be investigated and documented in order to determine whether changes can be instituted to prevent such occurrences in the future.

1910.1030(d)(3)(iii)

Accessibility. The employer shall ensure that appropriate personal protective equipment in the appropriate sizes is readily accessible at the worksite or is issued to employees. Hypoallergenic gloves, glove liners, powderless gloves, or other similar alternatives shall be readily accessible to those employees who are allergic to the gloves normally provided.

1910.1030(d)(3)(iv)

Cleaning, Laundering, and Disposal. The employer shall clean, launder, and dispose of personal protective equipment required by paragraphs (d) and (e) of this standard, at no cost to the employee.

1910.1030(d)(3)(v)

Repair and Replacement. The employer shall repair or replace personal protective equipment as needed to maintain its effectiveness, at no cost to the employee.

1910.1030(d)(3)(vi)

If a garment(s) is penetrated by blood or OPIM, the garment(s) shall be removed immediately or as soon as feasible.

1910.1030(d)(3)(vii)

All personal protective equipment shall be removed prior to leaving the work area.

1910.1030(d)(3)(viii)

When personal protective equipment is removed it shall be placed in an appropriately designated area or container for storage, washing, decontamination or disposal.

1910.1030(d)(3)(ix)

Gloves. Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, OPIM, mucous membranes, and non-intact skin; when performing vascular access procedures except as specified in paragraph (d)(3)(ix)(D); and when handling or touching contaminated items or surfaces.

1910.1030(d)(3)(ix)(A)

Disposable (single use) gloves such as surgical or examination gloves, shall be replaced as soon as practical when contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised.

1910.1030(d)(3)(ix)(B)

Disposable (single use) gloves shall not be washed or decontaminated for re-use.

1910.1030(d)(3)(ix)(C)

Utility gloves may be decontaminated for re-use if the integrity of the glove is not compromised. However, they must be discarded if they are cracked, peeling, torn, punctured, or exhibit other signs of deterioration or when their ability to function as a barrier is compromised.

1910.1030(d)(3)(ix)(D)

If an employer in a volunteer blood donation center judges that routine gloving for all phlebotomies is not necessary then the employer shall:

1910.1030(d)(3)(ix)(D)(1)

Periodically reevaluate this policy;

1910.1030(d)(3)(ix)(D)(2)

Make gloves available to all employees who wish to use them for phlebotomy;

1910.1030(d)(3)(ix)(D)(3)

Not discourage the use of gloves for phlebotomy; and

1910.1030(d)(3)(ix)(D)(4)

Require that gloves be used for phlebotomy in the following circumstances:

1910.1030(d)(3)(ix)(D)(4)(i)

When the employee has cuts, scratches, or other breaks in his or her skin;

1910.1030(d)(3)(ix)(D)(4)(ii)

When the employee judges that hand contamination with blood may occur, for example, when performing phlebotomy on an uncooperative source individual; and

1910.1030(d)(3)(ix)(D)(4)(iii)

When the employee is receiving training in phlebotomy.

1910.1030(d)(3)(x)

Masks, Eye Protection, and Face Shields. Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin- length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or OPIM may be generated and eye, nose, or mouth contamination can be reasonably anticipated.

1910.1030(d)(3)(xi)

Gowns, Aprons, and Other Protective Body Clothing. Appropriate protective clothing such as, but not limited to, gowns, aprons, lab coats, clinic jackets, or similar outer garments shall be worn in occupational exposure situations. The type and characteristics will depend upon the task and degree of exposure anticipated.

1910.1030(d)(3)(xii)

Surgical caps or hoods and / or shoe covers or boots shall be worn in instances when gross contamination can reasonably be anticipated (e.g., autopsies, orthopaedic surgery).

1910.1030(d)(4)

Housekeeping --

1910.1030(d)(4)(i)

General. Employers shall ensure that the worksite is maintained in a clean and sanitary condition. The employer shall determine and implement an appropriate written schedule for cleaning and method of decontamination based upon the location within the facility, type of surface to be cleaned, type of soil present, and tasks or procedures being performed in the area.

1910.1030(d)(4)(ii)

All equipment and environmental and working surfaces shall be cleaned and decontaminated after contact with blood or OPIM.

1910.1030(d)(4)(ii)(A)

Contaminated work surfaces shall be decontaminated with an appropriate disinfectant after completion of procedures; immediately or as soon as feasible when surfaces are overtly contaminated or after any spill of blood or OPIM; and at the end of the work shift if the surface may have become contaminated since the last cleaning.

1910.1030(d)(4)(ii)(B)

Protective coverings, such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper used to cover equipment and environmental surfaces, shall be removed and replaced as soon as feasible when they become overtly contaminated or at the end of the workshift if they may have become contaminated during the shift.

1910.1030(d)(4)(ii)(C)

All bins, pails, cans, and similar receptacles intended for reuse which have a reasonable likelihood for becoming contaminated with blood or OPIM shall be inspected and decontaminated on a regularly scheduled basis and cleaned and decontaminated immediately or as soon as feasible upon visible contamination.

1910.1030(d)(4)(ii)(D)

Broken glassware which may be contaminated shall not be picked up directly with the hands. It shall be cleaned up using mechanical means, such as a brush and dust pan, tongs, or forceps.

1910.1030(d)(4)(ii)(E)

Reusable sharps that are contaminated with blood or OPIM shall not be stored or processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed.

1910.1030(d)(4)(iii)

Regulated Waste --

1910.1030(d)(4)(iii)(A)

Contaminated Sharps Discarding and Containment.

1910.1030(d)(4)(iii)(A)(1)

Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are:

1910.1030(d)(4)(iii)(A)(1)(i)

Closable;

1910.1030(d)(4)(iii)(A)(1)(ii)

Puncture resistant;

1910.1030(d)(4)(iii)(A)(1)(iii)

Leakproof on sides and bottom; and

1910.1030(d)(4)(iii)(A)(1)(iv)

Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard.

1910.1030(d)(4)(iii)(A)(2)

During use, containers for contaminated sharps shall be:

1910.1030(d)(4)(iii)(A)(2)(i)

Easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found (e.g., laundries);

1910.1030(d)(4)(iii)(A)(2)(ii)

Maintained upright throughout use; and

1910.1030(d)(4)(iii)(A)(2)(iii)

Replaced routinely and not be allowed to overfill.

1910.1030(d)(4)(iii)(A)(3)

When moving containers of contaminated sharps from the area of use, the containers shall be:

1910.1030(d)(4)(iii)(A)(3)(i)

Closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping;

1910.1030(d)(4)(iii)(A)(3)(ii)

Placed in a secondary container if leakage is possible. The second container shall be:

1910.1030(d)(4)(iii)(A)(3)(ii)(A)

Closable;

1910.1030(d)(4)(iii)(A)(3)(ii)(B)

Constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping; and

1910.1030(d)(4)(iii)(A)(3)(ii)(C)

Labeled or color-coded according to paragraph (g)(1)(i) of this standard.

1910.1030(d)(4)(iii)(A)(4)
Reusable containers shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of percutaneous injury.

1910.1030(d)(4)(iii)(B)

Other Regulated Waste Containment --

1910.1030(d)(4)(iii)(B)(1)

Regulated waste shall be placed in containers which are:

1910.1030(d)(4)(iii)(B)(1)(i)

Closable;

1910.1030(d)(4)(iii)(B)(1)(ii)

Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;

1910.1030(d)(4)(iii)(B)(1)(iii)

Labeled or color-coded in accordance with paragraph (g)(1)(i) this standard; and

1910.1030(d)(4)(iii)(B)(1)(iv)

Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

1910.1030(d)(4)(iii)(B)(2)

If outside contamination of the regulated waste container occurs, it shall be placed in a second container. The second container shall be:

1910.1030(d)(4)(iii)(B)(2)(i)

Closable;

1910.1030(d)(4)(iii)(B)(2)(ii)

Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;

1910.1030(d)(4)(iii)(B)(2)(iii)

Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard; and

1910.1030(d)(4)(iii)(B)(2)(iv)

Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

1910.1030(d)(4)(iii)(C)

Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories.

1910.1030(d)(4)(iv)
Laundry.

1910.1030(d)(4)(iv)(A)

Contaminated laundry shall be handled as little as possible with a minimum of agitation.

1910.1030(d)(4)(iv)(A)(1)

Contaminated laundry shall be bagged or containerized at the location where it was used and shall not be sorted or rinsed in the location of use.

1910.1030(d)(4)(iv)(A)(2)

Contaminated laundry shall be placed and transported in bags or containers labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard. When a facility utilizes Universal Precautions in the handling of all soiled laundry, alternative labeling or color-coding is sufficient if it permits all employees to recognize the containers as requiring compliance with Universal Precautions.

1910.1030(d)(4)(iv)(A)(3)

Whenever contaminated laundry is wet and presents a reasonable likelihood of soak-through of or leakage from the bag or container, the laundry shall be placed and transported in bags or containers which prevent soak-through and / or leakage of fluids to the exterior.

1910.1030(d)(4)(iv)(B)

The employer shall ensure that employees who have contact with contaminated laundry wear protective gloves and other appropriate personal protective equipment.

1910.1030(d)(4)(iv)(C)

When a facility ships contaminated laundry off-site to a second facility which does not utilize Universal Precautions in the handling of all laundry, the facility generating the contaminated laundry must place such laundry in bags or containers which are labeled or color-coded in accordance with paragraph (g)(1)(i).

1910.1030(e)

HIV and HBV Research Laboratories and Production Facilities.

1910.1030(e)(1)

This paragraph applies to research laboratories and production facilities engaged in the culture, production, concentration, experimentation, and manipulation of HIV and HBV. It does not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissues, or organs. These requirements apply in addition to the other requirements of the standard.

1910.1030(e)(2)

Research laboratories and production facilities shall meet the following criteria:

1910.1030(e)(2)(i)

Standard Microbiological Practices. All regulated waste shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

1910.1030(e)(2)(ii)

Special Practices.

1910.1030(e)(2)(ii)(A)

Laboratory doors shall be kept closed when work involving HIV or HBV

is in progress.

1910.1030(e)(2)(ii)(B)

Contaminated materials that are to be decontaminated at a site away from the work area shall be placed in a durable, leakproof, labeled or color-coded container that is closed before being removed from the work area.

1910.1030(e)(2)(ii)(C)

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

1910.1030(e)(2)(ii)(D)

When OPIM or infected animals are present in the work area or containment module, a hazard warning sign incorporating the universal biohazard symbol shall be posted on all access doors. The hazard warning sign shall comply with paragraph (g)(1)(ii) of this standard.

1910.1030(e)(2)(ii)(E)

All activities involving OPIM shall be conducted in biological safety cabinets or other physical-containment devices within the containment module. No work with these OPIM shall be conducted on the open bench.

1910.1030(e)(2)(ii)(F)

Laboratory coats, gowns, smocks, uniforms, or other appropriate protective clothing shall be used in the work area and animal rooms. Protective clothing shall not be worn outside of the work area and shall be decontaminated before being laundered.

1910.1030(e)(2)(ii)(G)

Special care shall be taken to avoid skin contact with OPIM. Gloves shall be worn when handling infected animals and when making hand contact with OPIM is unavoidable.

1910.1030(e)(2)(ii)(H)

Before disposal all waste from work areas and from animal rooms shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

1910.1030(e)(2)(ii)(I)

Vacuum lines shall be protected with liquid disinfectant traps and high-efficiency particulate air (HEPA) filters or filters of equivalent or superior efficiency and which are checked routinely and maintained or replaced as necessary.

1910.1030(e)(2)(ii)(J)

Hypodermic needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle- locking syringes or disposable syringe-needle units (i.e., the needle is integral to the syringe) shall be used for the injection or aspiration of OPIM. Extreme caution shall be used when handling needles and syringes. A needle shall not be bent, sheared, replaced in the sheath or guard, or removed from the syringe following use. The needle and syringe shall be promptly placed in a puncture-resistant container and autoclaved or decontaminated before reuse or disposal.

1910.1030(e)(2)(ii)(K)

All spills shall be immediately contained and cleaned up by appropriate professional staff or others properly trained and equipped to work with potentially concentrated infectious materials.

1910.1030(e)(2)(ii)(L)

A spill or accident that results in an exposure incident shall be immediately reported to the laboratory director or other responsible person.

1910.1030(e)(2)(ii)(M)

A biosafety manual shall be prepared or adopted and periodically reviewed and updated at least annually or more often if necessary. Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures, and shall be required to follow them.

1910.1030(e)(2)(iii)

Containment Equipment.

1910.1030(e)(2)(iii)(A)

Certified biological safety cabinets (Class I, II, or III) or other appropriate combinations of personal protection or physical containment devices, such as special protective clothing, respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals, shall be used for all activities with OPIM that pose a threat of exposure to droplets, splashes, spills, or aerosols.

1910.1030(e)(2)(iii)(B)

Biological safety cabinets shall be certified when installed, whenever they are moved and at least annually.

1910.1030(e)(3)

HIV and HBV research laboratories shall meet the following criteria:

1910.1030(e)(3)(i)

Each laboratory shall contain a facility for hand washing and an eye wash facility which is readily available within the work area.

1910.1030(e)(3)(ii)

An autoclave for decontamination of regulated waste shall be available.

1910.1030(e)(4)

HIV and HBV production facilities shall meet the following criteria:

1910.1030(e)(4)(i)

The work areas shall be separated from areas that are open to unrestricted traffic flow within the building. Passage through two sets of doors shall be the basic requirement for entry into the work area from access corridors or other contiguous areas. Physical separation of the high-containment work area from access corridors or other areas or activities may also be provided by a double-doored clothes-change room (showers may be included), airlock, or other access facility that requires passing through two sets of doors before entering the work area.

1910.1030(e)(4)(ii)

The surfaces of doors, walls, floors and ceilings in the work area shall be water resistant so that they can be easily cleaned. Penetrations in these surfaces shall be sealed or capable of being sealed to facilitate decontamination.

1910.1030(e)(4)(iii)

Each work area shall contain a sink for washing hands and a readily available eye wash facility. The sink shall be foot, elbow, or automatically operated and shall be located near the exit door of the work area.

1910.1030(e)(4)(iv)

Access doors to the work area or containment module shall be self-closing.

1910.1030(e)(4)(v)

An autoclave for decontamination of regulated waste shall be available within or as near as possible to the work area.

1910.1030(e)(4)(vi)

A ducted exhaust-air ventilation system shall be provided. This system shall create directional airflow that draws air into the work area through the entry area. The exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside, and shall be dispersed away from occupied areas and air intakes. The proper direction of the airflow shall be verified (i.e., into the work area).

1910.1030(e)(5)

Training Requirements. Additional training requirements for employees in HIV and HBV research laboratories and HIV and HBV production facilities are specified in paragraph (g)(2)(ix).

1910.1030(f)

Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up --

1910.1030(f)(1)

General.

1910.1030(f)(1)(i)

The employer shall make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure, and post-exposure evaluation and follow-up to all employees who have had an exposure incident.

1910.1030(f)(1)(ii)

The employer shall ensure that all medical evaluations and procedures including the hepatitis B vaccine and vaccination series and post-exposure evaluation and follow-up, including prophylaxis, are:

1910.1030(f)(1)(ii)(A)

Made available at no cost to the employee;

1910.1030(f)(1)(ii)(B)

Made available to the employee at a reasonable time and place;

1910.1030(f)(1)(ii)(C)

Performed by or under the supervision of a licensed physician or by or under the supervision of another licensed healthcare professional; and

1910.1030(f)(1)(ii)(D)

Provided according to recommendations of the U.S. Public Health Service current at the time these evaluations and procedures take place, except as specified by this paragraph (f).

1910.1030(f)(1)(iii)

The employer shall ensure that all laboratory tests are conducted by an accredited laboratory at no cost to the employee.

1910.1030(f)(2)

Hepatitis B Vaccination.

1910.1030(f)(2)(i)

Hepatitis B vaccination shall be made available after the employee has received the training required in paragraph (g)(2)(vii)(I) and within 10 working days of initial assignment to all employees who have occupational exposure unless the employee has previously received the complete hepatitis B vaccination series, antibody testing has revealed that the employee is immune, or the vaccine is contraindicated for medical reasons.

1910.1030(f)(2)(ii)

The employer shall not make participation in a prescreening program a prerequisite for receiving hepatitis B vaccination.

1910.1030(f)(2)(iii)

If the employee initially declines hepatitis B vaccination but at a later date while still covered under the standard decides to accept the vaccination, the employer shall make available hepatitis B vaccination at that time.

1910.1030(f)(2)(iv)

The employer shall assure that employees who decline to accept hepatitis B vaccination offered by the employer sign the statement in Appendix A.

1910.1030(f)(2)(v)

If a routine booster dose(s) of hepatitis B vaccine is recommended by the U.S. Public Health Service at a future date, such booster dose(s) shall be made available in accordance with section (f)(1)(ii).

1910.1030(f)(3)

Post-exposure Evaluation and Follow-up. Following a report of an exposure incident, the employer shall make immediately available to the exposed employee a confidential medical evaluation and follow-up, including at least the following elements:

1910.1030(f)(3)(i)

Documentation of the route(s) of exposure, and the circumstances under which the exposure incident occurred;

1910.1030(f)(3)(ii)

Identification and documentation of the source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law;

1910.1030(f)(3)(ii)(A)

The source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV and HIV infectivity. If consent is not obtained, the employer shall 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, shall be tested and the results documented.

1910.1030(f)(3)(ii)(B)

When the source individual is already known to be infected with HBV or HIV, testing for the source individual's known HBV or HIV status need not be repeated.

1910.1030(f)(3)(ii)(C)

Results of the source individual's testing shall be made available to the exposed employee, and the employee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.

1910.1030(f)(3)(iii)

Collection and testing of blood for HBV and HIV serological status;

1910.1030(f)(3)(iii)(A)

The exposed employee's blood shall be collected as soon as feasible and tested after consent is obtained.

1910.1030(f)(3)(iii)(B)

If the employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, the sample shall 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 shall be done as soon as feasible.

1910.1030(f)(3)(iv)

Post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service;

1910.1030(f)(3)(v)

Counseling; and

1910.1030(f)(3)(vi)

Evaluation of reported illnesses.

1910.1030(f)(4)

Information Provided to the Healthcare Professional.

1910.1030(f)(4)(i)

The employer shall ensure that the healthcare professional responsible for the employee's Hepatitis B vaccination is provided a copy of this regulation.

1910.1030(f)(4)(ii)

The employer shall ensure that the healthcare professional evaluating an employee after an exposure incident is provided the following information:

1910.1030(f)(4)(ii)(A)

A copy of this regulation;

1910.1030(f)(4)(ii)(B)

A description of the exposed employee's duties as they relate to the exposure incident;

1910.1030(f)(4)(ii)(C)

Documentation of the route(s) of exposure and circumstances under which exposure occurred;

1910.1030(f)(4)(ii)(D)

Results of the source individual's blood testing, if available; and

1910.1030(f)(4)(ii)(E)

All medical records relevant to the appropriate treatment of the employee including vaccination status which are the employer's responsibility to maintain.

1910.1030(f)(5)

Healthcare Professional's Written Opinion. The employer shall obtain and provide the employee with a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the evaluation.

1910.1030(f)(5)(i)

The healthcare professional's written opinion for Hepatitis B vaccination shall be limited to whether Hepatitis B vaccination is indicated for an employee, and if the employee has received such vaccination.

1910.1030(f)(5)(ii)

The healthcare professional's written opinion for post- exposure evaluation and follow-up shall be limited to the following information:

1910.1030(f)(5)(ii)(A)

That the employee has been informed of the results of the evaluation; and

1910.1030(f)(5)(ii)(B)

That the employee has been told about any medical conditions resulting from exposure to blood or OPIM which require further evaluation or treatment.

1910.1030(f)(5)(iii)

All other findings or diagnoses shall remain confidential and shall not be included in the written report.

1910.1030(f)(6)

Medical Recordkeeping. Medical records required by this standard shall be maintained in accordance with paragraph (h)(1) of this section.

1910.1030(g)

Communication of Hazards to Employees --

1910.1030(g)(1)

Labels and Signs --

1910.1030(g)(1)(i)

Labels.

1910.1030(g)(1)(i)(A)

Warning labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or OPIM; and other containers used to store, transport or ship blood or OPIM, except as provided in paragraph (g)(1)(i)(E), (F) and (G).

1910.1030(g)(1)(i)(B)

Labels required by this section shall include the following legend:

Sample 2 Biohazard Symbol

1910.1030(g)(1)(i)(C)

These labels shall be fluorescent orange or orange-red or predominantly so, with lettering and symbols in a contrasting color.

1910.1030(g)(1)(i)(D)

Labels shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.

1910.1030(g)(1)(i)(E)

Red bags or red containers may be substituted for labels.

1910.1030(g)(1)(i)(F)

Containers of blood, blood components, or blood products that are labeled as to their contents and have been released for transfusion or other clinical use are exempted from the labeling requirements of paragraph (g).

1910.1030(g)(1)(i)(G)

Individual containers of blood or OPIM that are placed in a labeled container during storage, transport, shipment or disposal are exempted from the labeling requirement.

1910.1030(g)(1)(i)(H)

Labels required for contaminated equipment shall be in accordance with this paragraph and shall also state which portions of the equipment remain contaminated.

1910.1030(g)(1)(i)(I)

Regulated waste that has been decontaminated need not be labeled or color-coded.

1910.1030(g)(1)(ii)

Signs.

1910.1030(g)(1)(ii)(A)

The employer shall post signs at the entrance to work areas specified in paragraph (e), HIV and HBV Research Laboratory and Production Facilities, which shall bear the following legend:

Sample 2 Biohazard Symbol (Name of the Infectious Agent)
(Special requirements for entering the area) (Name, telephone number of the laboratory director or other responsible person.)

1910.1030(g)(1)(ii)(B)

These signs shall be fluorescent orange-red or predominantly so, with lettering and symbols in a contrasting color.

1910.1030(g)(2)

Information and Training.

1910.1030(g)(2)(i)

The employer shall train each employee with occupational exposure in accordance with the requirements of this section. Such training must be provided at no cost to the employee and during working hours. The employer shall institute a training program and ensure employee participation in the program.

1910.1030(g)(2)(ii)

Training shall be provided as follows:

1910.1030(g)(2)(ii)(A)

At the time of initial assignment to tasks where occupational exposure may take place;

1910.1030(g)(2)(ii)(B)

At least annually thereafter.

1910.1030(g)(2)(iii)
[Reserved]

1910.1030(g)(2)(iv)

Annual training for all employees shall be provided within one year of their previous training.

1910.1030(g)(2)(v)

Employers shall provide additional training when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the employee's occupational exposure. The additional training may be limited to addressing the new exposures created.

1910.1030(g)(2)(vi)

Material appropriate in content and vocabulary to educational level, literacy, and language of employees shall be used.

1910.1030(g)(2)(vii)

The training program shall contain at a minimum the following elements:

1910.1030(g)(2)(vii)(A)

An accessible copy of the regulatory text of this standard and an explanation of its contents;

1910.1030(g)(2)(vii)(B)

A general explanation of the epidemiology and symptoms of bloodborne diseases;

1910.1030(g)(2)(vii)(C)

An explanation of the modes of transmission of bloodborne pathogens;

1910.1030(g)(2)(vii)(D)

An explanation of the employer's exposure control plan and the means by which the employee can obtain a copy of the written plan;

1910.1030(g)(2)(vii)(E)

An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and OPIM;

1910.1030(g)(2)(vii)(F)

An explanation of the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, work practices, and personal protective equipment;

1910.1030(g)(2)(vii)(G)

Information on the types, proper use, location, removal, handling, decontamination and disposal of personal protective equipment;

1910.1030(g)(2)(vii)(H)

An explanation of the basis for selection of personal protective equipment;

1910.1030(g)(2)(vii)(I)

Information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge;

1910.1030(g)(2)(vii)(J)

Information on the appropriate actions to take and persons to contact in an emergency involving blood or OPIM;

1910.1030(g)(2)(vii)(K)

An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available;

1910.1030(g)(2)(vii)(L)

Information on the post-exposure evaluation and follow- up that the employer is required to provide for the employee following an exposure incident;

1910.1030(g)(2)(vii)(M)

An explanation of the signs and labels and / or color coding required by paragraph (g)(1); and

1910.1030(g)(2)(vii)(N)

An opportunity for interactive questions and answers with the person

conducting the training session.

1910.1030(g)(2)(viii)

The person conducting the training shall be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace that the training will address.

1910.1030(g)(2)(ix)

Additional Initial Training for Employees in HIV and HBV Laboratories and Production Facilities. Employees in HIV or HBV research laboratories and HIV or HBV production facilities shall receive the following initial training in addition to the above training requirements.

1910.1030(g)(2)(ix)(A)

The employer shall assure that employees demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with HIV or HBV.

1910.1030(g)(2)(ix)(B)

The employer shall assure that employees have prior experience in the handling of human pathogens or tissue cultures before working with HIV or HBV.

1910.1030(g)(2)(ix)(C)

The employer shall provide a training program to employees who have no prior experience in handling human pathogens. Initial work activities shall not include the handling of infectious agents. A progression of work activities shall be assigned as techniques are learned and proficiency is developed. The employer shall assure that employees participate in work activities involving infectious agents only after proficiency has been demonstrated.

1910.1030(h)

Recordkeeping --

1910.1030(h)(1)

Medical Records.

1910.1030(h)(1)(i)

The employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.1020.

1910.1030(h)(1)(ii)

This record shall include:

1910.1030(h)(1)(ii)(A)

The name and social security number of the employee;

1910.1030(h)(1)(ii)(B)

A copy of the employee's hepatitis B vaccination status including the dates of all the hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination as required by paragraph (f)(2);

1910.1030(h)(1)(ii)(C)

A copy of all results of examinations, medical testing, and follow-up procedures as required by paragraph (f)(3);

1910.1030(h)(1)(ii)(D)

The employer's copy of the healthcare professional's written opinion as required by paragraph (f)(5); and

1910.1030(h)(1)(ii)(E)

A copy of the information provided to the healthcare professional as required by paragraphs (f)(4)(ii)(B)(C) and (D).

1910.1030(h)(1)(iii)

Confidentiality. The employer shall ensure that employee medical records required by paragraph (h)(1) are:

1910.1030(h)(1)(iii)(A)

Kept confidential; and

1910.1030(h)(1)(iii)(B)

Not disclosed or reported without the employee's express written consent to any person within or outside the workplace except as required by this section or as may be required by law.

1910.1030(h)(1)(iv)

The employer shall maintain the records required by paragraph (h) for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.1020.

1910.1030(h)(2)

Training Records.

1910.1030(h)(2)(i)

Training records shall include the following information:

1910.1030(h)(2)(i)(A)

The dates of the training sessions;

1910.1030(h)(2)(i)(B)

The contents or a summary of the training sessions;

1910.1030(h)(2)(i)(C)

The names and qualifications of persons conducting the training; and

1910.1030(h)(2)(i)(D)

The names and job titles of all persons attending the training sessions.

1910.1030(h)(2)(ii)

Training records shall be maintained for 3 years from the date on which the training occurred.

1910.1030(h)(3)

Availability.

1910.1030(h)(3)(i)

The employer shall ensure that all records required to be maintained by this section shall be made available upon request to the Assistant Secretary and the Director for examination and copying.

1910.1030(h)(3)(ii)

Employee training records required by this paragraph shall be provided upon request for examination and copying to employees, to employee representatives, to the Director, and to the Assistant Secretary.

1910.1030(h)(3)(iii)

Employee medical records required by this paragraph shall be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the Director, and to the Assistant Secretary in accordance with 29 CFR 1910.1020.

1910.1030(h)(4)

Transfer of Records. The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.1020(h).

OSHA recently discovered mistakes made by the Federal Register editors of the CFR in implementing the 2001 OSHA final rule for Bloodborne Pathogens; these mistakes affected 29 CFR 1910.1030(h) and (i). OSHA is in the process of correcting these mistakes in the CFR. In the meantime, OSHA is revising this website to reflect the correct regulations as they will soon appear in eCFR and in the July 1, 2012, edition of the hard copy CFR. We will remove this notice from this website when the Federal Register editors make the necessary corrections in the eCFR.

1910.1030(h)(5)

Sharps injury log.

1910.1030(h)(5)(i)

The employer shall establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee. The sharps injury log shall contain, at a minimum:

1910.1030(h)(5)(i)(A)

The type and brand of device involved in the incident,

1910.1030(h)(5)(i)(B)

The department or work area where the exposure incident occurred, and

1910.1030(h)(5)(i)(C)

An explanation of how the incident occurred.

1910.1030(h)(5)(ii)

The requirement to establish and maintain a sharps injury log shall apply to any employer who is required to maintain a log of occupational injuries and illnesses under 29 CFR part 1904.

1910.1030(h)(5)(iii)

The sharps injury log shall be maintained for the period required by 29 CFR 1904.33.

1910.1030(i)

Dates —

1910.1030(i)(1)

Effective Date. The standard shall become effective on March 6, 1992.

1910.1030(i)(2)

The Exposure Control Plan required by paragraph (c) of this section shall be completed on or before May 5, 1992.

1910.1030(i)(3)

Paragraphs (g)(2) Information and Training and (h) Recordkeeping of this section shall take effect on or before June 4, 1992.

1910.1030(i)(4)

Paragraphs (d)(2) Engineering and Work Practice Controls, (d)(3) Personal Protective Equipment, (d)(4) Housekeeping, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, and (g)(1) Labels and Signs of this section, shall take effect July 6, 1992.

[56 FR 64004, Dec. 06, 1991, as amended at 57 FR 12717, April 13, 1992; 57 FR 29206, July 1, 1992; 61 FR 5507, Feb. 13, 1996; 66 FR 5325 Jan., 18, 2001; 71 FR 16672 and 16673, April 3, 2006; 73 FR 75586, Dec. 12, 2008; 76 FR 33608, June 8, 2011; 76 FR 80740, Dec. 27, 2011; 77 FR 19934, April 3, 2012]

Appendix M: Contact Information and Guidance Links

Office of Environmental Health and Safety Mainline: 801-581-6590

E Mail: Biosafety@ehs.utah.edu

IBC Website: https://IBC.Utah.edu

IBC Policies: https://ibc.utah.edu/biosafety-policies.php

IBC Fact Sheets and SOP library: https://ibc.utah.edu/library.php

IBC Training Matrix: https://ibc.utah.edu/training.php

EHS Website: https://oehs.utah.edu/

Safety Administrative Management System (SAM):
https://oehs.utah.edu/topics/lab-management-system