

Weber State University

Biohazard and rDNA Safety Program



WEBER STATE
UNIVERSITY

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If you have suggestions to improve this program,
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A. INTRODUCTION

DEFINITION OF BIO-HAZARDOUS MATERIALS

Bio-hazardous materials are those materials of biological origin that could potentially cause harm to humans, domestic or wild animals, or plants. Examples include recombinant DNA; transgenic animals or plants, human, animal or plant pathogens; biological toxins (such as tetanus toxin); human blood and certain human body fluids; and human or primate cell cultures.

PURPOSE

The purpose of the Weber State University Biosafety Program is to assist in protecting faculty, staff and students from exposure to bio-hazardous materials, to guard against the release of bio-hazardous materials that may harm humans, animals or the environment, and to protect the integrity of experimental materials. The Biosafety Program seeks to fulfill these goals by providing support for the Institutional Biosafety Committee (IBC), managing the Bloodborne Pathogen Exposure Control Plan, and consulting on exposure assessments for the Occupational Health Program. Environmental Health and Safety (EHS) is available to assist with obtaining permits and shipping bio-hazardous materials, advise staff who work with bio-hazardous materials, and oversee proper disposal of bio-hazardous wastes. This manual outlines appropriate practices, university policies and regulatory requirements for working safely with bio-hazardous materials. Additionally, EHS staffs a Biosafety Officer (BSO) who is available to assist researchers in determining appropriate practices and facilities for bio-containment, proper bio-hazardous waste disposal methods, which regulatory guidelines apply to their research projects, shipping requirements for bio-hazardous materials, and whether any special permits are needed.

RESPONSIBILITIES

Weber State University

The president of the Weber State University is ultimately responsible for all environmental health and safety issues at the institution. This responsibility is exercised through the normal chain of authority within the university by delegating the charge for ensuring safe work practices and adherence to established policies and guidelines to the provost, vice-presidents, deans, directors, department chairs, principal investigators (PI), supervisors and, ultimately, each employee.

Environmental Health and Safety (EH&S)

EHS is responsible for the development and oversight of proper management practices for all bio-hazardous materials at the Weber State University, including developing and implementing policies for the Weber State University. EHS is also responsible for ensuring that affected departments are aware of the university policies and regulatory guidelines regarding the proper use of bio-hazardous materials.

Supervisors

Principal investigators, instructors and supervisors are primarily responsible for ensuring that the policies and guidelines established in this manual are strictly followed by all personnel under their jurisdiction, including other researchers.

Individual Personnel

Individuals who work with bio-hazardous materials have a responsibility to follow the guidelines presented in this manual and to consult with their supervisors regarding the safe handling and proper disposal of specific bio-hazardous materials used in their work area.

Pregnant women, individuals who are immuno-compromised or have other health conditions are advised to consult the Material Safety Data Sheets (MSDS) for all hazardous chemicals, radioactive materials and pathogenic organisms in their environment in order to determine if any risks exist. They should also

consult with their supervisor, Occupational Medicine or their physician of choice concerning potential risks and how to manage those risks.

Biohazards and the Institutional Biosafety Committee

The Institutional Biosafety Committee has established and implemented policies that provide for the safe conduct of recombinant DNA research and that ensure compliance with the NIH guidelines. The IBC is comprised of at least five members who collectively have experience and expertise in recombinant DNA technology. They possess the capability to assess the safety of recombinant DNA research and to identify any potential risk to public health or the environment. Two members are not affiliated with the College (apart from their membership on the IBC) and represent the interest of the surrounding community with respect to health and protection of the environment. The Biological Safety Officer also serves as member. The IBC is responsible for reviewing recombinant DNA research conducted at or sponsored by the College for compliance with the NIH guidelines as specified in Section III of the guidelines. The committee approves those research projects that are found to conform to the NIH guidelines. This review shall include:

- An independent assessment of the containment levels required by the NIH guidelines for the proposed research.
- Assessment of the facilities, procedures, practices, and training and expertise of personnel involved in recombinant DNA research.
- Notifying the principal investigator of the results of the committee's review.
- Reviewing recombinant DNA research conducted at Weber State University to ensure compliance with the NIH guidelines.
- Adopting emergency plans covering accidental spills and personnel contamination resulting from recombinant DNA research.
- Reporting any significant problems with or violations of the NIH guidelines and any significant research-related accidents or illnesses to the appropriate institutional official and NIH/Office of Biotechnology Activities (OBA) within 30 days.
- Establishing subcommittees or ad hoc committees as necessary to carry out its overall responsibilities.

Biological Safety Officer

The Biological Safety Officer's duties include, but are not limited to:

- Periodic inspections to ensure that laboratory standards are rigorously followed (Note: laboratories are periodically inspected as part of the laboratory safety program).
- Reporting to the IBC and the College any significant problems, violations of the NIH guidelines, and any significant research-related accidents or illnesses.
- Developing emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving recombinant DNA research.
- Providing advice on laboratory security.
- Providing technical advice to principal investigators and the IBC on laboratory safety procedures.

Principal Investigator

The principal investigator is responsible for full compliance with the NIH guidelines in the conduct of recombinant DNA research. As part of this responsibility, the principal investigator shall:

- Make an initial determination of the required levels of physical and biological containment in accordance with the NIH guidelines.
- Select appropriate microbiological practices and laboratory techniques to be used for the research.
- Submit the initial research protocol and any subsequent changes (e.g., changes in the source of DNA or host-vector system), if covered under Sections III-A, III-B, III-C, III-D, or III-E of the guidelines, to the IBC for review and approval or disapproval.
- Remain in communication with the IBC throughout the duration of the project.
- Make available to all laboratory staff the protocols that describe the potential biohazards and the precautions to be taken.

- Instruct and train laboratory staff in the practices and techniques required to ensure safety and the procedures for dealing with accidents.
- Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed.
- Investigate and report any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the Biological Safety Officer, the IBC, NIH/OBA, and other appropriate authorities.
- Correct work errors and conditions that may result in the release of recombinant DNA materials.
- Ensure the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity and genotypic and phenotypic characteristics).
- Initiate or modify no recombinant DNA research which requires IBC approval prior to initiation (see Sections III-A, III-B, III-C, and III-D of the guidelines) until that research or the proposed modification thereof has been approved by the IBC and has met all other requirements of the NIH guidelines.
- Determine whether experiments are covered by Section III-E of the guidelines and ensure that the appropriate procedures are followed.
- Report any significant problems, violations of the NIH guidelines, or any significant research-related accidents and illnesses to the Biological Safety Officer, IBC, NIH/OBA, and other appropriate authorities (if applicable) within 30 days.
- Report any new information bearing on the NIH guidelines to the IBC and to NIH/OBA.
- Be adequately trained in good microbiological techniques adhere to IBC-approved emergency plans for handling accidental spills and personnel contamination.
- Comply with shipping requirements for recombinant DNA molecules.

Submissions by the Principal Investigator to the NIH/OBA are covered in section IV-B-7-b of the NIH guidelines. For example, these submissions can cover certifying of new host-vector systems or determining level of containment. See the guidelines for exact requirements.

B. APPLICABLE REGULATIONS AND GUIDELINES

The following federal and international regulations and guidelines apply to work performed with potentially bio- hazardous materials:

ANIMALS OR ANIMAL PRODUCTS

U.S. Department of Agriculture (USDA) Import-Export Regulations (7 CFR.)

- Animals and animal products import/transport permits issued by the Animal and Plant Health Inspection Service (APHIS) Veterinary Services branch.
- Quick reference and applications available at the **USDA Import-Export Directory**.

U.S. Department of Agriculture (USDA) Interstate Transfer of Infectious Agents Regulations (9 CFR 122).

- APHIS requires permits for interstate movement of animal pathogens of veterinary or agricultural significance.
- Recipient must have a valid APHIS/VS permit, renewed annually.

BIOLOGICAL SAFETY CABINETS

NSF Standard 49 for the Evaluation of Class II Laminar Flow Biological Safety Cabinets.

- Information on the NSF Biohazard Cabinetry Program, which sets the criteria for standard methods by which biological safety cabinets are to be tested in order to be certified.

HUMAN BLOOD, OTHER POTENTIALLY INFECTIOUS HUMAN BODY FLUIDS OR TISSUES, HUMAN CELL LINES

U.S. Occupational Safety and Health Administration (OSHA) Blood borne Pathogen Standard (29 CFR 1910.1030.)

- See Weber State University's, *Blood borne Pathogen Exposure Control Plan* available from EHS.

INFECTIOUS AGENTS AND BIOLOGICAL TOXINS

Biosafety in Microbiological and Biomedical Laboratories.

- Guidelines for infectious agent use published by the Centers for Disease Control and Prevention (CDC) and the NIH (National Institutes of Health). See:
<http://www.cdc.gov/biosafety/publications/bmb15/>

U.S. Public Health Service (USPHS) Select Agents Regulations (42 CFR 73, 9 CFR 121 and 7 CFR 331).

- CDC Importation Permits for Etiologic Agents.

Centers for Disease Control and Prevention's (CDC's) Additional Requirements for Facilities Transferring or Receiving Select Agents (42 CFR 72).

- Registration program for shipping infectious agents or biological toxins defined as "Select Agents" at: <http://www.selectagents.gov/>

PLANTS OR PLANT PESTS

USDA Import-Export Regulations (7 CFR).

- Plant and plant pest import/export permits issued by the APHIS Plant Protection and Quarantine branch.

RECOMBINANT DNA

NIH "Guidelines for Research Involving Recombinant DNA Molecules".

- Federal Register, May 7, 1986 and amendments
- Available on the Internet at http://oba.od.nih.gov/rdna/nih_guidelines_oba.html .

USDA Introduction of Genetically Engineered Organisms Regulations (7 CFR 340).

- Biotechnology transport/introduction permits issued by the APHIS Biotechnology and Scientific Services branch.
- Available on the Internet at
- **User's Guide for Introducing Genetically Engineered Plants and Microorganisms** available online.

SHIPPING BIOHAZARDOUS MATERIALS

U.S. Department of Transportation (DOT) Dangerous Goods Regulations (49 CFR 100-185).

- Requirements for transport of hazardous materials.

International Civil Aviation Organization (ICAO) Technical Instructions on the Safe Transport of Dangerous Goods by Air.

- International requirements for air transport of hazardous materials.
- Purchasing information available online.

International Air Transport Association Dangerous Goods Regulations

- Manual for international air transport of hazardous materials, based on the ICAO's "Technical Instructions on the Safe Transport of Dangerous Goods by Air".

BIOHAZARDOUS WASTE DISPOSAL

U.S. Environmental Protection Agency (EPA) Hospital/Medical/Infectious Waste Incinerators Regulations (40 CFR 62.)

- Emissions requirements for hospital, medical and infectious waste incinerators

C. USE OF RECOMBINANT DNA, INFECTIOUS AGENTS OR BIOLOGICAL TOXINS

The IBC must approve any research project that involves the use of:

- recombinant DNA, including transgenic animals or plants,
- Agents infectious to humans or animals, such as pathogenic bacteria or viruses,
- Biological toxins, such as tetanus toxin or aflatoxin.

Note that the use of radioactive materials requires the approval of the Radiation Safety Committee.

APPLICATION AND AUTHORIZATION

The Principal Investigator (PI) must complete the **rDNA Registration Form** as appropriate and submit it to the Biosafety Officer. If the work requires IBC review and approval, the **BIOLOGICAL AGENT RESEARCH for IBC Submission Form** must be completed.

If the project is approved by the IBC, a signed authorization form specifying any special conditions under which authorization is granted will be forwarded to the PI. If approval is denied, a written notification will be sent to the PI. This notification will explain the decision, and will identify possible modifications to the project that would allow approval.

ANNUAL RENEWAL

Authorization for projects involving the use of recombinant DNA, infectious agents or biological toxins must be renewed annually. A reauthorization form will be sent to the PI sixty days before the authorization anniversary date.

D. MEDICAL SURVEILLANCE

The Occupational Health Program provides medical surveillance for all personnel who are exposed to identified or regulated risks and for personnel with animal contact.

Workplace exposure to human blood and other potentially infectious materials (OPIM), as defined by the OSHA Blood borne Pathogen Standard (29 CFR 1910.1030), requires medical surveillance and annual Blood borne Pathogen Exposure Control Training. Weber State University has a written Blood borne Pathogen Exposure Control Plan (see Appendix III).

VACCINATIONS

Personnel who work with human pathogens must be offered the choice of receiving a vaccine, if available, and informed of the risks associated with the vaccine. Personnel working with human blood or OPIM must be offered the Hepatitis B vaccination. Vaccinations will be administered by University Health Center and billed to the PI.

For Hepatitis B vaccinations, a Hepatitis B Immunization Form must be completed (see Appendix II). Affected personnel choosing to receive the vaccination will be asked to complete the Hepatitis B Immunization Form, giving consent for the immunization. The consent form will be filed in the person's file at Environmental

Health and Safety. Affected personnel choosing not to receive a vaccination must complete the Hepatitis B Immunization Form, signing the declination portion instead. The department supervisor will ensure the completed and signed declination form is placed in the person's department personnel file.

IF AN EXPOSURE OCCURS

Before beginning work with human pathogens, human blood or OPIM, all applicable safety information for a specific pathogen must be reviewed (see web site address for Infectious Agents MSDS from Health Canada's Laboratory Centre for Disease Control in Appendix IV, or call the Biosafety Officer). If available, safety information will be sent to the PI with the IBC authorization form when the research project is approved. Familiarity with exposure routes, symptoms and treatment methods will provide better preparation for the possibility of exposure to the human pathogen, human blood or OPIM being used. If exposure to a human pathogen, human blood or OPIM occurs or is suspected to have occurred while at work, the appropriate medical treatment should be sought immediately.

E. BIOHAZARD CONTROL PRACTICES

WORK PRACTICES (FIRST LINE OF DEFENSE)

Safe lab practice is the most critical part of preventing exposure when working with rDNA and bio-hazardous materials. The best laboratory and safety equipment in the world cannot provide protection without good work practices and adequate training.

TRAINING AND EDUCATION

Anyone planning to work with rDNA and bio-hazardous materials must be adequately trained before beginning the work. Supervisors are responsible for ensuring that all personnel receive proper training. Annual refresher training is also recommended to ensure continued safety. Information communicated in the training should include:

- A discussion of this manual and how it applies to activities conducted in specific work areas,
- An explanation of the health hazards, signs and symptoms of exposure to rDNA and bio-hazardous materials used in specific work areas,
- A description of actions personnel can take to protect themselves from exposure, such as special work practices, use of safety equipment, vaccinations, emergency procedures, etc.
- Procedures to follow in case of an exposure or spill, including incident reporting and reporting requirement to outside entities (DEQ, OSHA, NIH for example)

EHS has a variety of biosafety and other safety-related training videos that may be checked out by Weber State University personnel. See Appendix V for a list of titles.

SIGNS AND LABELING

Anyone entering areas where rDNA and bio-hazardous materials are used must be aware of the potential hazards. Biohazard signs should be posted on doors to rooms where microorganisms, rDNA or biological toxins known to cause disease in humans are used, such as microorganisms classified as Biosafety Level 2 or greater. Red or orange biohazard labels should be placed on containers and storage units (refrigerators, freezers, incubators, waste containers, etc.) that are used for microorganisms, rDNA or biological toxins causing disease in humans. Contaminated equipment must be labeled as well. Animal biohazard signs should be posted where strict animal pathogens are used. Door signs may be requested from EHS.

LABORATORY PRACTICE AND TECHNIQUE

Workplace-acquired infections are rare, but not unheard of. In order for infection and disease to occur, there must be an adequate number of organisms to cause disease (infectious dose) and a route of entry into the body. Knowing how infectious organisms are transmitted and what their infectious dose is can help in evaluating the risk and avoiding infection. Information about the organism(s) should be gathered prior to commencing work with them. Good starting points for safety information about human pathogens are MSDSs (see Infectious Agents MSDSs in Appendix IV) and the “Agent Summary Statements” from Biosafety in Microbiological and Biomedical Laboratories.

Infectious agents are transmitted through one or more of these routes of exposure:

- sharps injuries (needle sticks, cuts with contaminated broken glass, etc., also known as parenteral exposure),
- inhalation of aerosols (microscopic solid or liquid particles small enough to remain dispersed and suspended in air for long periods; about 5 micrometers or less in diameter),
- ingestion,
- Mucous membrane exposure (including the eyes, inside of the mouth and nose, and the genitals).

Using work practices that block routes of exposure can prevent workplace infection. Good microbiological techniques must always be used in the laboratory.

- Eating, drinking, smoking, applying cosmetics or storing food in laboratories is strictly prohibited. Potentially contaminated hands should be kept away from the mouth, eyes, and non-intact skin.
- Hands should be washed frequently, even after wearing gloves, and scrubbed vigorously with soap and water for a full 30 seconds (as long as it takes to sing “Happy Birthday”). The physical removal of organisms from the skin is just as important as using a disinfectant.
- Work surfaces and equipment must be decontaminated immediately after using rDNA or bio-hazardous materials.
- Wearing appropriate personal protective equipment (PPE) blocks potential routes of exposure.

More specific suggestions for common laboratory procedures used with rDNA or bio-hazardous materials follow. Each prevents rDNA or bio-hazardous materials from entering the body through common exposure routes.

Pipetting: *The greatest risks with pipetting are the creation of aerosols and splashing.*

- Mouth pipetting is prohibited. Mechanical pipetting aids should be used instead.
- All rDNA or bio-hazardous materials should be pipetted in a biosafety cabinet if possible.
- Cotton-plugged pipets should be used.
- Bio-hazardous or rDNA materials must never be forcibly discharged from pipets. “To deliver” pipets should be used instead of pipets requiring blowout.
- After using reusable pipets for BSL-2 or greater, they should be placed horizontally in a pan filled with enough liquid disinfectant to completely cover them and the entire pan autoclaved before cleaning the pipets for reuse.
- When working in a biosafety cabinet, all waste and/or disinfecting containers must be kept inside the cabinet while they are being used.

Centrifuging: *The greatest risk with centrifuging is the creation of aerosols.*

- Sealed tubes and safety buckets that seal with O-rings should be used. To avoid spills from broken tubes, the tubes, O-rings and buckets should be inspected for damage before each use.
- Leaks can be prevented by not overfilling centrifuge tubes. The outside of the tubes should be wiped with disinfectant after they are filled and sealed.

- Rotors and centrifuge tubes should be opened inside a biosafety cabinet. If a biosafety cabinet is not available, a minimum of 10 minutes settling time should be allowed before opening.

Using Needles, Syringes, and Other Sharps: *The greatest risks when using sharps are accidental injection and the creation of aerosols.*

- Needles and syringes should only be used when there is no reasonable alternative. Safety needles and syringes should be used in these instances.
- The sharp should be kept away from the fingers as much as possible. Sharps should never be bent, sheared, recapped, nor have needles removed from syringes after use. If a contaminated needle must be recapped or removed from the syringe, a mechanical device, such as a forceps, must be used.
- Air bubbles should be minimized when filling a syringe. A pad moistened with disinfectant must be placed over the tip of the needle when expelling air. Work should be performed in a biosafety cabinet whenever possible.
- An appropriate sharps container must be kept close to the work area to avoid walking around with contaminated sharps. Care should be taken not to overfill sharps containers. They are considered full when they are 2/3 filled. The rDNA and Biohazard Waste Guidelines details proper disposal methods (see Appendix III).

Blending, Grinding, Soliciting, Lyophilizing: *The greatest risk when using any of these devices is the creation of aerosols.*

- Blenders, grinders, sollicitors, lyophilizes, etc. should be operated in a biosafety cabinet whenever possible.
- Safety blenders should be used. Safety blenders are designed to prevent leakage from the bottom of the blender jar and to withstand sterilization by autoclaving. They also provide a cooling jacket to avoid biological inactivation.
- Avoiding glass blender jars prevents breakage. If a glass jar must be used, it must be covered with a polypropylene jar to contain the glass in case of breakage.
- A towel moistened with disinfectant must be placed over the top of the blender while operating. This practice can be adapted to grinders and sollicitors as well.
- Aerosols must be allowed to settle for five minutes before opening the blender jar (or grinder or sollicitor container).
- Lyophilize vacuum pump exhaust should be filtered through HEPA filters or vented into a biosafety cabinet.
- Polypropylene tubes should be used in place of glass ampoules for storing bio-hazardous material in liquid nitrogen. Ampoules can explode, causing eye injuries and exposure to the bio-hazardous material.

Sterilizing Inoculating Loops: *the greatest risk when sterilizing inoculating loops in an open flame (such as with a Bunsen burner) is the creation of aerosols, which may contain viable microorganisms.*

- A shielded electric incinerator or hot bead sterilizer should be used to minimize aerosol production. Disposable plastic loops and needles are good alternatives.

PERSONAL PROTECTIVE EQUIPMENT

Appropriate PPE is chosen by considering the potential routes of exposure that need to be blocked to prevent exposure and infection. It is essential that PPE be removed before leaving the laboratory or animal room. PPE must never be taken home. It should be disposed of or laundered in the work area where it is used.

Lab Coats and Closed Toe Shoes: *Lab coats, scrub suits, gowns, and closed-toe shoes prevent rDNA or bio-hazardous materials from reaching skin, and more importantly, any cuts, dermatitis, etc. that may be present. They also protect street clothing from needing decontamination, as well as preventing contamination*

of laboratory cultures from the normal flora present on the skin.

- At minimum, a long-sleeved lab coat and closed-toe shoes must be worn in any microbiology laboratory. Long sleeves minimize contamination of skin and street clothes and reduce shedding of microorganisms from the skin. Closed shoes protect the feet from spills and injuries from dropped sharps.
- Elastic-cuffed lab coats help prevent spills caused by catching the cuff on laboratory equipment. When working with rDNA or bio-hazardous materials inside a biosafety cabinet, elastic cuffs prevent contaminated air from being blown up the lab coat sleeve into the breathing zone.
- Lab coats must remain in the laboratory when personnel go home or to non-laboratory work areas. This keeps any contamination in the laboratory instead of spreading it to other work areas or homes.

Gloves: *Gloves prevent exposure of the skin, and any cuts, dermatitis, etc. that may be present, to bio-hazardous materials.*

- Nitrile gloves will prevent exposure to microorganisms. However, gloves must be compatible with the chemicals being handled, as well as offering protection from rDNA or bio-hazardous materials. EHS can provide assistance with choosing appropriate gloves.
- For the best protection, the cuffs of the gloves should overlap the lower sleeves of the laboratory coat.
- Disposable gloves must not be reused. They are designed for disposal after one use or if exposed to a chemical (they offer limited chemical protection). Utility gloves, such as rubber dishwashing gloves may be disinfected for re-use if they do not show signs of wear or degradation.
- EHS can provide assistance finding an alternative for those allergic to gloves (most common with latex) and/or the powder they contain.

Eye and Face Protection: *Eye and face protection prevent splashes into the eyes, nose and mouth (mucous membrane exposure), and onto the skin.*

- Goggles or safety glasses should be worn to protect the eyes.
- Full-face shields should be worn to protect facial skin.

Respirators: *Respirators prevent the inhalation of aerosolized microorganisms (inhalation exposure) when safety equipment designed to contain infectious aerosols, such as a biosafety cabinet, is not available.*

- EHS can provide assistance in determining the appropriate respirator needed.
- Respirator training and fit-testing is required for certain respirators. The **Respiratory Protection Program** provides details. EHS can assist in determining if a respirator is needed.

LABORATORY SAFETY SURVEYS

The Weber State University Biosafety Checklist (Appendix II), used for surveys completed by EHS, includes criteria for work with infectious agents (from the CDC/NIH publication Biosafety in Microbiological and Biomedical Laboratories, Section B) and for work with recombinant DNA (from the NIH “Guidelines for Research Involving Recombinant DNA,”). Using the “Laboratory Safety Survey Checklist” and the “Biosafety Checklist” (Appendix II) on a regular basis will help ensure that good laboratory safety practices are being used.

ANIMAL HANDLING

Animals on Campus: *The spread of infectious agents between animal populations can be prevented and laboratory personnel can be protected from zoonotic agents by adhering to the following basic guidelines, required by Animal Care Services and wherever animals are housed or used on campus.*

- Shoe covers must be worn, when specified, upon entering an animal room.
- All animal room doors must remain closed at all times, except for entering and exiting.

- Disposable gloves must be worn when handling animals, bedding or soiled cages.
- Disposable or washable outer garments (such as lab coats, gowns, coveralls) must be worn to protect personal clothing from contamination when working with animals.
- Eating, drinking smoking, applying cosmetics and handling contact lenses in animal rooms or procedure rooms is prohibited.
- Hand contact with the nose, eyes, or mouth is strongly discouraged when working with animals.
- Hands must be washed with soap and water immediately after handling any animals or animal equipment, and before leaving the animal facility or laboratory.
- Extra caution must be taken with needles or other sharp equipment used with animals. Needles shall remain capped until ready to use, and then promptly and properly disposed. The rDNA and Bio-hazardous Waste Disposal Guidelines details proper procedures (see Appendix III).
- Handling only those species for which proper handling training has been provided can prevent injury.
- Any bites or other wounds must be washed immediately with soap and water and appropriate medical attention sought.
- Unauthorized persons are prohibited from entering animal rooms. Additional requirements may be specified for certain research studies.

Animals in the Field: Fieldwork involving wild animals requires adapting the basic animal infection control guidelines to the particular situation in the field. One of the major concerns with fieldwork is exposure to wild rodents that might carry Hantavirus or other zoonotic diseases. Personnel working in areas where they are likely to be exposed to wild rodents or their nesting areas must consult with EHS.

CELL AND TISSUE CULTURE

Cell cultures may contain viruses. It is prudent to consider all cell lines to be potentially infectious. Most cell cultures can be safely manipulated using BL2 practices and containment.

- If cells are known or suspected to contain a specific pathogen or oncogenic virus, appropriate biosafety practices for handling that virus must be used when working with the cell culture.
- All primary and permanent cell lines must be handled using BL2 practices and containment.
- BL1 practices and containment may be used for cell lines that meet all of the following criteria:

Cells must be: well-established, non-primate, non-human, confirmed not to contain a primate virus, pathogenic bacteria, mycoplasma or fungi.

SAFETY EQUIPMENT (PRIMARY CONTAINMENT)

Primary containment equipment is designed to reduce or eliminate exposure to rDNA or bio-hazardous materials. Biological safety cabinets are the principal piece of primary containment equipment commonly found in the laboratory. Other types of primary containment equipment include sealed centrifuge cups and special airtight enclosures designed to contain specific laboratory equipment (such as solenoids), which are likely to produce aerosols of rDNA or bio-hazardous materials.

BIOLOGICAL SAFETY CABINETS

What is a Biological Safety Cabinet?

A biological safety cabinet (BSC) is not a chemical fume hood. Chemical fume hoods are designed to protect personnel by removing chemical fumes and aerosols away from the work area. BSCs are designed to protect both personnel and the products being handled from particulate hazards, such as infectious microorganisms or rDNA. BSCs use uniform vertical laminar airflow to create a barrier to airborne particulates. BSCs also contain High Efficiency Particulate Air (HEPA) filters to clean both the air entering the work area and the air exhausted to the environment. The air in most BSCs is partially recirculated over the work area through the HEPA filter before being exhausted to the environment. The HEPA filter removes airborne particles from the air, but does not remove chemical fumes. A single exception is a specific special

model of Class II Type B2 BSC that is also UL-classified as a fume hood. The Centers for Disease Control and Prevention's (CDC) booklet Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets provide more detailed information on the different types of BSCs (see Appendix IV).

When Should I Use a BSC?

A BSC should be used when manipulations that are likely to create aerosols (such as vortexing open tubes, pipetting, opening caps after centrifuging, sonicating or aspirating with a syringe) are performed on antineoplastic, rDNA or human pathogens classified as BL2 or higher.

Open Flames in a BSC:

Open flames, such as Bunsen burners, should never be used in a BSC. Open flames inside of a BSC disrupt the airflow, compromising protection of both the worker and the work. Open flames are extremely dangerous around flammable materials, such as ethanol, which is often found in a BSC. Electric incinerators or disposable inoculating loops can be used instead.

Decontamination and Ultraviolet Lights in a BSC:

The BSC work area must always be cleaned and disinfected thoroughly, using a chemical disinfectant such as an iodophor, after each use. Ultraviolet (UV) light has very little power to penetrate, even through a dust particle, so the UV light in a BSC is only useful as a secondary disinfecting step to keep the work area decontaminated between uses. UV lights are also a hazard for eyes, and proper precautions need to be used to prevent exposure during use.

Annual Certification Testing:

To ensure that BSCs are providing necessary protection to workers and the environment, testing should be done according to the internationally accepted standards of NSF International. Each BSC should have a label on it stating the date it was last certified. The Biosafety Officer will schedule annual recertification visits by a licensed technician.

Moving or Repairs:

Filter changes and repairs must be done by a qualified servicing company. BSCs must be recertified annually, whenever they are moved, or have filters changed.

Purchasing and Installing a New BSC:

If plans exist for the purchase of a new BSC, the Biosafety Officer should be notified to provide assistance in choosing the appropriate BSC. The following purchasing and installation guidelines must be followed:

- The BSC must be certified by NSF International according to NSF Standard 49. Work with any infectious agents or recombinant DNA classified as requiring BL2 or higher containment will not be permitted in a BSC that does not pass certification testing for containment.
- The Biosafety Officer must verify that the BSC type (Class II Type A, Class II Type B2, etc.) is appropriate for the work to be done.
- Any outlets inside the work area of the BSC should be ground fault circuit interrupter (GFCI) outlets.
- Installation of BSCs must allow access to both supply and exhaust filters for annual certification testing and filter changes.
- Top of cabinet must be far enough below the ceiling (at least 18") to allow field-testing of exhaust flow according to NSF Standard 49.
- Any connections to exhaust ductwork must allow access for field-testing of exhaust flow according to NSF Standard 49.
- If the BSC is a Class II Type B3, the preferred connection to the exhaust is a thimble connection and not a gas-tight connection. Additional details about choosing appropriate BSCs and their proper use are published by the CDC in a booklet titled Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets (see Appendix IV).

FACILITY DESIGN (SECONDARY CONTAINMENT)

Laboratories intended for work with bio-hazardous materials are designed to contain those materials in the laboratory so that they cannot cause harm to the general public or the environment. If a laboratory is to be used for work with recombinant DNA, infectious agents or biological toxins, it must meet certain federal criteria regarding appropriate containment facilities for the specific work to be done. The level of work that a laboratory is qualified to do is referred to as the biosafety level. There are four defined biosafety levels, BL1, BL2, BL3 and BL4. The CDC/NIH publication *Biosafety in Microbiological and Biomedical Laboratories* can be referenced.

BIOSAFETY LEVELS – RISK GROUPS

Table 1: Classification of Infectious Microorganisms by Risk Group

Risk Group Classification	NIH Guidelines for Research involving Recombinant DNA Molecule
Risk Group 1	Agents not associated with disease in healthy adult humans.
Risk Group 2	Agents associated with human disease that is rarely serious and for which preventive or therapeutic interventions are <i>often</i> available.
Risk Group 3	Agents associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk).
Risk Group 4	Agents likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk).

Table 2: Relationship of Risk Groups, Biosafety Levels and Containment

Risk Group	BSL Level	Examples	Practices	Facilities, Equipment
1	Basic BSL 1	Basic Teaching, Research	Good Microbiological Techniques (GMT)	None required; open bench work, directional
2	Basic BSL 2	Primary health services, diagnostic, teaching, public health	Level 1 plus protective clothing, biohazard signage	Open bench plus Biological Safety Cabinet (BSC) for aerosols
3	Containment BSL 3	Special diagnostic, research	Level 2 plus special clothing, controlled access	BSC and/or other primary containment devices for all activities

Animal biosafety levels describe similar levels for containment facilities and practices necessary when vertebrate animals are infected with infectious agents. Plant biosafety levels describe similar levels for containment facilities and practices necessary for recombinant plants, plant pathogens or plant pests. All laboratories on campus may qualify as BL1 or BL2. There are no laboratories on campus that qualify as BL3 or BL4. Therefore, work with materials requiring BL3 or BL4 containment is prohibited in laboratories on campus.

F. DISPOSAL AND DISINFECTION OF rDNA or BIOHAZARDOUS MATERIALS

UNIVERSITY POLICIES

The rDNA or Bio-hazardous Waste Disposal Guidelines (Appendix III) specifies proper procedures for treatment and disposal of rDNA or bio-hazardous waste, according to applicable federal, state, local and university policies. The “rDNA or Bio-hazardous Waste Disposal Guidelines” form (Appendix II) may be copied and posted near waste handling areas in the laboratory for quick reference.

SUPPLIES

Most supplies for decontaminating rDNA or bio-hazardous waste, such as autoclavable waste bags, sharps containers and labels, may be purchased through Science Stores (Appendix VI). The Biosafety Officer can provide advice with finding supplies for special disposal needs.

AUTOCLAVES

Effective Autoclave Use:

Autoclaves must be used properly to effectively decontaminate potentially bio-hazardous or rDNA materials. The following elements all contribute to autoclave effectiveness.

Temperature and Pressure:

Adequate chamber temperature is at least 121°C (250°F). Adequate chamber pressure is 15 psi.

Time:

Adequate autoclaving time is a minimum of 30 minutes, measured after the temperature of the material being sterilized reaches 121°C and 15 psi pressure. The tighter the autoclave is packed, the longer it will take to reach 121°C in the center of the load.

Contact:

Steam saturation of the load is essential for effective decontamination. To ensure steam saturation, autoclave bags should be left partially open during autoclaving to allow steam to penetrate into the bag. Adding a small amount of water to the bag helps ensure heat transfer to the items being decontaminated. Water must not be added if it will cause bio-hazardous or rDNA materials to splash out of the bag.

Containers:

Autoclavable items must be placed in leak-proof containers. Plastic bags must be placed inside a secondary container in the autoclave in case liquids leak out. Plastic or stainless steel containers are appropriate secondary containers. Plastic bags and pans must be autoclavable, so that the plastic will not melt.

Indicators:

Tape indicators can only verify that the autoclave has reached normal operating temperatures for decontamination. Most chemical indicators change color after being exposed to 121°C, but cannot measure the

length of time spent at 121°C. Biological indicators (such as *Bacillus stearothermophilus* spore strips) and certain chemical indicators (such as Sterigage) verify that the autoclave reached adequate temperature for a long enough time to kill microorganisms. A simple chemical indicator, measuring temperature only, should be used in every load to monitor the effectiveness of individual autoclave runs (temperature only). Once a month, either a biological indicator (such as *Bacillus stearothermophilus* spore strips) or a more complete chemical indicator, measuring both time and temperature (such as Sterigage), should be used. The indicator must be buried in the center of the load to validate adequate steam penetration. Results should be recorded in a logbook.

AUTOCLAVE SAFETY

Autoclaves are classified as pressure vessels and must be inspected at least annually. Repairs to most autoclaves on campus are done by Facilities. Because an autoclave uses saturated steam under high pressure to achieve sterilizing temperatures, proper use is important to ensure operator safety. Injuries can be prevented when using the autoclave by observing the following rules:

Heat-resistant gloves, eye protection and a lab coat must be worn, especially when unloading the autoclave.

- Steam burns and shattered glassware can be prevented by ensuring that the pressure in the autoclave chamber is near zero before opening the door at the end of a cycle. The autoclave door should be cracked open slowly to allow the steam to escape gradually.
- Items must be allowed to cool for 10 minutes before removing them from the autoclave.
- Sealed containers must never be put in an autoclave. They can explode. Large bottles with narrow necks may also explode if filled too full of liquid.
- Solvents, volatile or corrosive chemicals (such as phenol, chloroform, bleach, etc.), and radioactive materials must never be placed in an autoclave. EHS can provide assistance with any questions about proper disposal of these materials.
- Autoclave components must be inspected regularly. In particular, cleaning the drain screen frequently will help to prevent operation problems and down time. If a problem is discovered, repair must be initiated. An autoclave should never be operated until it has been properly repaired.

CHEMICAL DISINFECTANTS

Items that cannot be autoclaved can generally be decontaminated using a chemical disinfectant. The choice of chemical disinfectant depends on the surface or item needing decontamination, as well as the particular organism requiring inactivation.

Choosing a Chemical Disinfectant

When choosing a chemical disinfectant, the MSDS (if available) for the agent needing inactivation, the categories of disinfectants listed in this section and the disinfectant product label should be referenced. Personnel in the process of choosing a disinfectant should also keep in mind the following considerations:

- a) How **effective** is the disinfectant for the particular application?
 - What is the organism requiring inactivation? (Different disinfectants are more effective against different types of organisms.)
 - How many of the organisms are present? (The more organisms present, the more disinfectant required and/or the longer the application time will be.)
 - What needs decontamination? (The disinfectant must be compatible with the item to be decontaminated.)
 - Work surfaces (for example, metal, tile, plastic, wood, concrete)
 - Glassware
 - Equipment (such as biosafety cabinet, surgical tools, cages)
 - Liquids for disposal

- Does organic matter inactivate the disinfectant? (Proteins in organic matter can inactivate or slow down the activity of certain disinfectants.)
 - What is the shelf life of the disinfectant?
- b) The **hazards** of the disinfectant.
- Is the disinfectant an eye, skin or respiratory irritant? (If yes, proper PPE is required during use.)
 - Is the disinfectant toxic by skin absorption, ingestion or inhalation? (If yes, proper PPE is required during use.)
 - Is the disinfectant corrosive to equipment or work surfaces?
 - Does the disinfectant leave a residue?
 - Is the disinfectant an environmental hazard (toxic to fish)?

TYPES OF CHEMICAL DISINFECTANTS

The following are outlines of the basic properties and examples of the most common categories of chemical disinfectants, including alcohols, chlorine compounds, liquid formaldehyde, glutaraldehyde, iodophors, peracetic acid, phenolic compounds, and quaternary ammonium compounds.

Alcohols (ethanol, isopropanol):

- Most effective against lipophilic viruses, less effective against non-lipid viruses, and ineffective against bacterial spores.
- Effective concentration is 70% to 90%.
- Evaporate quickly, so sufficient contact time may be difficult to achieve. Concentrations above 90% are less effective because of increased evaporation rate.

Chlorine compounds (household bleach – 5.25% sodium hypochlorite):

- Effective against vegetative bacteria and most viruses in solutions of 50-500 ppm available chlorine. Bacterial spores require concentrations of 2500 ppm with extended exposure time.
- A 5000-ppm available chlorine solution is preferred for general use because excess organic materials inactivate chlorine compounds. Diluting household bleach 1:10 with water makes this type of solution.
- Air and light inactivate diluted solutions, so solutions should be freshly made in order to maintain adequate available chlorine concentrations.
- Strong oxidizers thus are very corrosive to metal surfaces, as well as to skin, eyes and respiratory tract.

G. BIOHAZARD and rDNA SPILL CLEAN UP

The following protocol is generic, and is intended for use with microorganisms classified as BL2 or lower. The right protocol for any situation depends on the specific bio-hazardous or rDNA material used, the quantity of material spilled, and the location of the spill. Questions about spill clean-up or the use of organisms classified, as BL3 or BL4 should be directed to the Biosafety Officer. If a bio-hazardous or rDNA spill also includes radioactive material, the clean-up protocol may need to be modified. For these situations, the Radiation Safety Officer (during the regular workday), or EHS, if after hours, is available to answer any clean-up questions.

BIOHAZARD or rDNA SPILL KIT

Each laboratory using bio-hazardous or rDNA materials should have appropriate equipment and supplies on hand for managing spills and accidents involving bio-hazardous or rDNA materials. Permanent equipment should include a safety shower, eyewash, and a hand-washing sink and supplies. A Biohazard or rDNA Spill Kit should also be kept on hand. The supplies available in a Biohazard or rDNA Spill Kit should include, but are not limited to:

- A copy of these biohazard or rDNA spill clean-up instructions,

- Nitrile disposable gloves (8 mil),
- Lab coat(s),
- Safety goggles,
- N95 dust mask respirator(s),
- Disposable shoe covers (booties),
- Absorbent material, such as absorbent paper towels, granular absorbent material, etc.,
- All-purpose disinfectant, such as normal household bleach (freshly diluted 1:10) or an iodophor,
- Autoclavable bucket for diluting disinfectant (this can be used to store the kit contents when not in use),
- Tongs and/or forceps, and/or dust pan and hand broom or squeegee, etc. (for picking up broken glass or other contaminated sharps),
- Sharps waste container(s),
- Autoclavable biohazard waste bags,
- Biohazard or rDNA spill warning signs.

All non-disposable items should be autoclavable or compatible with the disinfectant to be used. Most of the listed items, as well as other biohazard or rDNA spill control items, are available at Science Stores, and often are contained within various commercially available biohazard or rDNA spill control kits.

SPILL CLEAN-UP PROTOCOL

- a) Any potentially contaminated clothing must be removed and placed in a biohazard waste bag for autoclaving.
 - If the spill is outside of a laboratory, immediate clean-up is essential. If outdoors, personnel should remain upwind from the spill, if at all possible.
 - If the spill is inside a centrifuge, the centrifuges should be closed as soon as the spill is noticed.
 - If the spill is contained inside a BSC, the BSC must remain running.
- b) Hands and any other contaminated skin must be washed thoroughly with soap and water.
- c) Everyone not needed for spill clean up must be cautioned to stay away from the spill area. Signs may be posted if necessary.
 - EHS is available to assist with spills that occur outside of a laboratory. If at all possible, laboratory personnel should appoint someone to call so they may remain and secure the site.
- d) Appropriate PPE must be worn. At minimum, disposable gloves, eye protection and a lab coat should be worn. An N95 dust mask respirator is advised for spills greater than ~10 ml outside a BSC, or any spill inside a centrifuge, because of the likelihood of splashing and/or aerosolization of the bio-hazardous or rDNA material.
- e) Any sharp contaminated objects must be removed from the spill area using mechanical means, never with hands.
- f) After all sharps are removed, disinfectant must be poured carefully around the edges of the spill, with care to avoid splashing. Paper towels can be used to absorb as much of the spilled material as possible. Working from the outside of the spill toward the center avoids spreading the contamination.
 - If the spill is inside a centrifuge, the rotor and its contents should be moved to a BSC, if possible.
 - If the spill is inside a BSC, the spill tray underneath the work area and the trough below the air intake grill must be cleaned as well. These are likely to be contaminated when the spill is large.
 - Note: Alcohol is not recommended as a disinfectant for large spills, especially inside a BSC, because large amounts of alcohol vapors create an explosion hazard.
- g) After initial clean-up, the spill area must be flooded with disinfectant and left to soak for at least 20 minutes (adequate contact time is important to ensure complete decontamination).
- h) Disinfectant can be absorbed with paper towels. A final wipe-down should be done with clean paper towels soaked with disinfectant. Laboratory personnel should be sure to disinfect any equipment, walls or other areas likely to have been splashed by the spill.
- i) All contaminated waste must be disposed of properly.
- j) Hands must be washed thoroughly with soap and water. If the spill is inside a BSC, the cabinet should

be left running for at least 10 minutes before resuming use.

- k) Any incident if a spill or exposure involving rDNA needs to be reported to EHS Biosafety Officer. The NIH has a reporting requirement in the event of a significant research-related accident or problems, within 30 days of the event.

H. TRANSPORTING AND SHIPPING BIOHAZARDOUS or rDNA MATERIALS

ON-CAMPUS TRANSPORT OF BIOHAZARDOUS or rDNA MATERIALS

Any bio-hazardous or rDNA materials transported between laboratories or buildings on campus should be contained, as they would be in the laboratory, to prevent release of the materials into the environment. Transport containers should be labeled with the biohazard symbol and the identity of the material inside. For example, to transport a rack of test tubes containing biohazard 2 organisms from a laboratory to another:

- The tubes should be capped and placed inside a sealed, puncture-resistant, unbreakable secondary container with a biohazard label indicating BSL-2. The secondary container must contain the samples in case the person carrying the container drops it while carrying it. Transport of any “Select Agents” between laboratories or buildings on campus also requires that records be kept of the amount and locations. The select agent regulation is described in the following section.

OFF-CAMPUS TRANSPORT OF BIOHAZARDOUS or rDNA MATERIALS BY COMMERCIAL CARRIERS

All off-campus transport of bio-hazardous or rDNA materials by commercial carriers must comply with federal and state shipping and permitting requirements, as described in the following sections. Off-campus includes across town to a collaborative research facility, out of town within the state, out of state in the U.S., and out of the country.

PERMIT REQUIREMENTS

Special federal permits may be required for importing and/or transporting human pathogens, animal pathogens, animals or animal products, plant pathogens or plant pests, and plants or plant products or rDNA. Permit requirements should be verified well in advance of needing the material in question, because some permits can take several weeks to receive. EHS and the Biosafety Officer can provide assistance with any questions about shipping and/or required permits for biological or rDNA materials.

Animals, Plants, Introduction of Genetically Modified Organisms

The USDA, through its Animal and Plant Health Inspection Service (APHIS), regulates transport of materials that could potentially harm U.S. agricultural products, such as livestock or crops. For this reason, APHIS permits may be required for import, export and/or transport of animal or plant pathogens, import or export of animals, animal products, plants or plant products, or introduction of genetically modified organisms into the environment. The information contained on the APHIS web site and the Biosafety Officer can help determine if a permit is required and assist with the application process.

USDA Animal and Plant Health Inspection Service Import-Export Directory

Special packaging may also be required for shipping these materials. The “Packaging and Paperwork Requirements” information, listed later in this section, provides details.

Human Pathogens or Biological Toxins

The Department of Health and Human Services, through the CDC, regulates transport of biological materials that could cause illness in humans. These regulated biological materials include pathogenic bacteria or viruses, toxins from biological sources (for example, tetanus toxin, aflatoxin, etc.), blood or tissues

suspected of containing diseases transmissible to humans and certain animals, and insects that may harbor disease causing organisms. The information contained on the CDC web site and the Biosafety Officer can help determine if a permit is required as assist with the application process.

Centers for Disease Control and Prevention's Importation Permits for Etiologic Agents

Special packaging may also be required for shipping these materials. The "Packaging and Paperwork Requirements" section provides details.

Select Agent Human Pathogens and Biological Toxins

The Department of Health and Human Services rule "Additional Requirements for Facilities Transferring or Receiving Select Agents," which expanded the regulations that were already in existence, went into effect in 1997. Facilities sending out or receiving certain designated Select Agents, such as certain specified viruses, bacteria, rickettsia, fungi and biological toxins, are now required to apply for and receive a Site Registration Number from the CDC before any shipments occur. Substantial criminal penalties apply to both individuals and organizations that do not comply with the regulation requirements. The Weber State University currently has an exempt status, because we do not hold, use or transfer threshold quantities of Select Agents. Separate paperwork must be completed for each laboratory on campus that will be sending out and/or receiving shipments of any of the Select Agents covered by this regulation, as well as for each Select Agent used. The paperwork consists of an extensive application packet requiring completion every three years. Registered laboratories are subject to inspection by outside agencies. The CDC web site and the Biosafety Officer can help determine whether the Select Agent rule applies to specific projects and whether registration is necessary.

PACKAGING AND PAPERWORK REQUIREMENTS

Any product that is or contains a hazardous material must be transported according to the requirements outlined in the Department of Transportation's (DOT) Title 49 regulations. This includes hazardous biological agents. To comply with DOT regulations, all hazardous materials must be properly classified, packaged, documented and handled. If the regulatory requirements for hazardous materials shipments are not met, citations and fines may be levied. The regulations also require Hazardous Materials Shipping Training for personnel involved in the transportation of hazardous materials. If it is necessary to ship a hazardous material:

- Required permit(s) must be obtained and hazard information collected regarding the product to be shipped,
- EHS can provide advice in acquiring approved packaging and proper classification,
- Approved packaging must be obtained,
- The product must be packaged under the direction of EHS and according to any package instructions,
- The package and paperwork may be delivered to the carrier directly.

The "Shipping Biological Materials Guide" in Appendix III provides more detailed information, including lists of packaging suppliers and commercial carriers.

OFF-CAMPUS TRANSPORT OF BIO-HAZARDOUS OR rDNA MATERIALS BY NON-COMMERCIAL ROUTES

All off-campus transport of bio-hazardous or rDNA materials by non-commercial routes must comply with the "Guidelines for Transport of Infectious Materials by Non-Commercial Routes" in Appendix III.

- Weber State University personnel may transport bio-hazardous or rDNA materials by non-commercial routes only in university vehicles. Personal vehicles may not be used due to insurance coverage limitations.
- Transport by non-commercial routes may only be done within the state of Utah.
- Some materials may never be transported via non-commercial routes. These materials are listed in the above-mentioned guidelines.

J. BIOHAZARDOUS or rDNA MATERIALS SECURITY

Although most microbiology laboratories contain a variety of dangerous biological, chemical and radioactive materials, these materials have rarely been used to intentionally injure anyone. However, there is growing concern about the possible use of biological or rDNA, chemical and radioactive materials by terrorists. In response to these concerns, the CDC has included guidelines to address laboratory security issues in the current edition of Biosafety in Microbiological and Biomedical Laboratories (see Section VI):

<http://www.cdc.gov/biosafety/publications/bmb15/>. Security is most critical for laboratories using biological agents, rDNA or toxins capable of causing serious or fatal illness to humans or animals, or causing serious damage to indigenous plants. All laboratories, however, should consider the following basic points of security and how they might apply to their individual situations. All laboratory personnel are responsible for:

- Controlling access to areas where bio-hazardous agents, rDNA or toxins are used and stored, and for locking refrigerators/freezers used to store Select Agents,
- Knowing who is in the laboratory,
- Knowing what materials are brought into the laboratory,
- Knowing what materials are removed from the laboratory,
- Reporting any undocumented visitors, missing biological, rDNA, chemical or radioactive materials, unusual or threatening phone calls, etc. to the laboratory supervisor, EHS and/or DPS.

APPENDIX I. PRINCIPAL INVESTIGATOR CHECKLIST FOR BIOHAZARDOUS or rDNA MATERIALS USE

Using this checklist to ensure that proper procedures have been followed before beginning work with potentially bio-hazardous materials, such as recombinant DNA, transgenic animals or plants; human, animal or plant pathogens; biological toxins, human blood or certain human body fluids; or human or monkey cell cultures.

APPENDIX II. FORMS

- **Biological Agent Registration-rDNA and BIOLOGICAL AGENT RESEARCH for IBC Submission Forms**
(Application for Use of Recombinant DNA, Infectious Agents or Biological Toxins)
- **Biosafety Checklist**
- **Hepatitis B Immunization Form**

APPENDIX III. UNIVERSITY POLICIES & GUIDELINES

WEBSITE ADDRESSES:

- **Bloodborne Pathogen Exposure Control Plan**
<http://www.weber.edu/EHS/biological.html>
- **Bio-hazardous or rDNA Waste Disposal Guidelines**
- **Autoclave Use Guidelines (pressure vessel monitoring).**
- **Shipping Biological or rDNA Materials Guide**
- **Guidelines for Transport of Infectious Materials by Non-Commercial Routes**

APPENDIX IV. RESOURCE LIST (WEBSITES)

RECOMBINANT DNA REGULATIONS

- **NIH Guidelines for Research Involving Recombinant DNA Molecules, May, 1999 (64CFR25361)**
http://oba.od.nih.gov/rdna/nih_guidelines_oba.html
- **Transport and Introduction of Genetically Engineered Materials (USDA/APHIS)**
http://www.aphis.usda.gov/import_export/index.shtml
The USDA Biotechnology Permits Branch website provides guidance on obtaining a permit or notification for the importation, interstate movement or introduction of genetically engineered plants and microorganisms into the environment.
- **INFECTIOUS AGENTS AND LABORATORY SAFETY**
Biosafety in Microbiological and Biomedical Laboratories, 5th Edition
The CDC/NIH guidelines for infectious agent use:
<http://www.cdc.gov/biosafety/publications/bmbl5/>
- **Infectious Agents MSDS from Health Canada's Laboratory Centre for Disease Control**
<http://www.phac-aspc.gc.ca/msds-ftss/>
Quick safety references for infectious organisms in an MSDS format from Health Canada's Laboratory Centre for Disease Control

- **TRANSPORT AND SHIPPING**
Import and Transport of Infectious Agents (CDC Regulations)
CDC Importation Permits for Etiologic Agents
<http://www.selectagents.gov/Regulations.html>
- **Additional Requirements for Facilities Transferring or Receiving Select Agents (42CFR72.6)**
CDC Laboratory Registration and Select Agent Transfer Program
<http://www.selectagents.gov/>
- **Import and Transport of Animal Products (USDA/APHIS regulations)**
USDA Animal and Plant Health Inspection Service - Veterinary Services Import-Export Directory
- **Import and transport of plant products, plant pests and plant pathogens (USDA/APHIS regulations)**
USDA Animal and Plant Health Inspection Service Agricultural Permit Directory
http://www.aphis.usda.gov/import_export/index.shtml
- **BIOLOGICAL SAFETY CABINETS**
Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets
<http://www.cdc.gov/biosafety/publications/index.htm>
- **NSF Standard 49 for the Evaluation of Class II Laminar Flow Biological Safety Cabinets**
Information on the NSF Biohazard Cabinetry Program, which sets the criteria for standard methods by which BSCs are to be tested in order to be certified.
<http://www.nsf.org/>

APPENDIX V. BIOSAFETY-RELATED VIDEOS

The following videos are available to be checked out from the EHS office. Call to reserve a video.

BLOODBORNE PATHOGENS

Bloodborne Pathogens (Take Precaution)

Coastal safety & Environmental, 18 minutes

Addresses OSHA's Bloodborne Pathogen Standard requirements with descriptions of general principles applicable to both laboratory and non-laboratory situations in which personnel may be exposed to blood borne pathogens on the job.

LABORATORY SAFETY

Laboratory Safety (The Finer Points)

Coastal safety & Environmental, 18 minutes

They say that practice always makes perfect. Through this program, seasoned laboratory employees can review safety techniques and general procedures they may have forgotten since their initial training. Based on OSHA 1910.1450, it covers:

- Hazardous materials in labs
- Fume hoods
- Emergency showers and eyewashes
- Chemical storage
- Using chemicals safely.

APPENDIX VI. BIOSAFETY RELATED SUPPLIES ON CAMPUS

SCIENCE STORES:

Disinfectants

Gloves

Labels and Signs

Sharps Waste Containers

Waste Bags

Registration #: _____

Weber State University
Department of Environmental Health & Safety
Recombinant DNA Registration

Directions: Please complete this form to register recombinant DNA research with the University Biosafety Committee (UBC) as required by the most current "Guidelines for Research Involving Recombinant DNA Molecules" (NIH Guidelines) and University Policy.

Submit a separate form for each project. **For questions, please contact the EH&S at 626-7823.**

Section I - to be completed for all projects

Principal Investigator: _____

Department: _____

Address: _____

Phone Number: _____ Fax: _____

Email: _____

Labs to be used: _____

For exempt work: General Work Description: _____

For non-exempt (covered) work: Project Title: _____

Proposed start date for research: _____

Your signature below indicates that you acknowledge all requirements and restrictions of the most current NIH Guidelines for the biosafety level you have indicated, unless modified by the UBC, that you accept responsibility for the safe conduct of the experiments conducted at this biosafety level and that you have informed all associated personnel of the conditions required for this work. It is the Principal Investigator's responsibility to follow the NIH Guidelines and notify the Biosafety Officer and the UBC of any adverse events, including research-related accidents and illnesses. The Principal Investigator certifies that the work description is accurate. Any work performed, which is not approved under this permit, may be subject to the loss of grant funds. This registration must be updated annually.

Signature of Investigator: _____ Date: _____

Section II - to be completed for all projects

Check the appropriate registration category for experiments covered by the NIH Guidelines:

All categories are defined in the NIH Guidelines

A. Experiments, which are, exempt and do not require registration.

_____ Examples include rDNA that is: not in organisms and viruses; entirely DNA segments from a single nonchromosomal or viral DNA source; entirely from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host or when transferred to another host by well established physiological means; entirely from a eukaryotic host when propagated only in that host or a closely related strain of the same species; entirely segments from different species that exchange DNA by known physiological processes; or not a significant risk to health or the environment.

If work is exempt, attach a description of the recombinant DNA procedures to be performed.

B. Experiments that Require IBC Approval, Recombinant DNA Advisory Committee Review, and NIH Director Approval Before Initiation.

_____ Deliberate transfer of a drug resistance trait to a microorganism that is not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.

C. Experiments that Require NIH/ORDA and IBC Approval Before Initiation.

_____ Cloning of toxin molecules with LD50 of less than 100 Nano grams per kilogram body weight.

D. Experiments that Require IBC Approval, Human Subjects Approval, and NIH/ORDA Registration Before Initiation. Submit completed Appendix M, I-V from the NIH Guidelines along with this document.

_____ Deliberate transfer of recombinant DNA or DNA or RNA derived from recombinant DNA into one or more human subjects (human gene transfer).

E. Experiments that Require IBC Approval Before Initiation.

_____ Experiments using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems.

_____ Experiments in which DNA from Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is cloned into nonpathogenic prokaryotic or lower eukaryotic Host-Vector Systems.

_____ Use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems.

_____ Experiments involving recombinant DNA in animals or transgenic whole animals.

_____ Experiments involving whole plants, to include exotic infectious agents that may impact ecosystems, transmissible exotic infectious agents in the presence of their specific arthropod vectors, sequences encoding vertebrate toxins introduced into plants or associated organisms, or microbial pathogens of insects/animals associated with plants if microorganism may impact ecosystem.

_____ Experiments involving more than 10 liters of culture.

F. Experiments that Require IBC Notice Simultaneous with Initiation.

_____ Formation of recombinant DNA molecules containing no more than two-thirds of the genome of any eukaryotic virus in tissue culture with no helper virus.

_____ Recombinant DNA modified plants that are noxious weeds or can interbreed with noxious weeds. Plants associated with recombinant DNA modified non-exotic microorganisms which have the potential for serious impact on ecosystems. Recombinant DNA modified arthropods or small animals associated with plants if these materials have no serious impact on ecosystems.

_____ Experiments involving recombinant DNA modified whole plants or organisms (if not included in Category E5 above).

_____ Generation of transgenic rodents where genome is altered by stable introduction of rDNA into germ line, if it requires only BSL1 containment.

Section III- to be completed for covered (non-exempt) projects only

1. Names of individuals participating in project, with job title: _____
2. Source(s) of DNA/RNA sequences (include genus, species, gene name and abbreviation): _____
3. Is a vector required? Yes _____ No _____
If yes, identify specific phage, plasmid, or virus:
Virus vector: Adenovirus _____ Retrovirus _____ Other _____
Defective: Yes No
Replication competent: Yes _____ No _____
If viral vector, what percent of the viral genome remains? _____
4. If the recombinant contains viral DNA, does the insert represent more than 2/3 of the viral genome? Yes _____ No _____
5. Is a helper virus required? Yes _____ No _____ If yes, specify: _____
6. What is the biological activity of the gene product or sequence inserted? _____
7. Will a deliberate attempt be made to obtain expression of the foreign gene encoded in the recombinant DNA? Yes _____ No _____
8. Host strain for propagation of the recombinant (give genus, species, and parent strain): _____
9. Target recipient of recombinant DNA (indicate species or cell lines used):
Animals: _____ Tissue Culture: _____
Plant cells: _____ Plants: _____
Gene therapy: _____
Specify target host(s) - human, animal species: _____
10. Proposed biosafety level for project (check one): 1 _____ 2 _____ 3 _____
11. Have all personnel involved in this project been trained to the appropriate biosafety level?
Yes _____ No _____
12. Dual Use Research- Check any categories below that apply to your project:
_____ Renders a useful vaccine ineffective.
_____ Adds antibiotic resistance affecting response to a clinically useful drug.
_____ Enhances pathogen virulence.

- _____ Increases pathogen transmissibility.
- _____ Widens a pathogen's host range.
- _____ Enables a pathogen to evade diagnostic or detection modalities.
- _____ Weaponization (e.g. environmental stabilization of pathogens).
- _____ None of the above.

13. Be sure to attach a description of the recombinant DNA procedures to this form. Include the following items: nature and purpose of the project; outline the procedures and techniques; risk to personnel; practices/equipment/facilities to protect the personnel; methods to inactivate and dispose of the agents. Sufficient detail must be provided to understand the project and review the rDNA procedures.

Section IV- For UBC Use Only

_____ Project/work exempt from recombinant DNA NIH Guidelines.
(**Make sure Work Description is attached**).

_____ Project/work requires registration according to NIH Guidelines. The PI and staff can safely perform this work with the training, work practices, and lab facilities listed.

The following signatures indicate provisional approval by the University Biosafety Committee for this project involving recombinant DNA technology. The work is to be performed according to NIH requirements. Final approval for projects that are NOT exempt from the NIH Guidelines will not be granted until after review by the entire UBC at the next meeting. Non-exempt work covered under this approval cannot begin until final approval is received.

UBC Member Conducting Review

Print Name: _____

Signature: _____

Date: _____

Biosafety Officer

Print Name: _____

Signature: _____

Date: _____

Expiration date: _____

Final UBC approval date: _____

UBC Representative Signature: _____

UBC Comments: _____

Hepatitis B Vaccination Form

You have the right to request or decline the hepatitis B (HBV) vaccination series. You should have already received training on the risks and prevention of occupational exposure to bloodborne pathogens, including HBV, and had an opportunity to ask questions. If you have not completed the training, please do so before filling out this form. If you have received the training:

1. Select Option A, B or C below, and fill in your name, employee ID/UIN number, and date.
2. Print and sign the completed form and send it to your institution's hepatitis B immunization contact person.

Option A – Accept the Vaccination (REQUEST TO RECEIVE HEPATITIS B VACCINE)

I have been informed of the biological hazards that exist in my workplace, and I understand the risks of exposure to blood or other potentially infectious materials involved with my job. I understand that I may be at risk of acquiring hepatitis B virus (HBV) infection. I acknowledge that I have been provided information on the hepatitis B vaccine, including information on its effectiveness, safety, and method of administration and the benefits of being vaccinated. I have been given the opportunity to be vaccinated with hepatitis B vaccine at no charge to myself. I request to receive the vaccination series.

Employee's Name (printed) _____
Employee's signature _____
Employee ID no. _____
Date (mm/dd/yyyy)

Option B – Already Immunized (STATEMENT OF CURRENT IMMUNIZATION)

I attest that I have already been immunized against hepatitis B virus (HBV) infection.

Employee's Name (printed) _____
Employee's signature _____
Employee ID no. _____
Date (mm/dd/yyyy)

Option C – Decline to be immunized (HEPATITIS B VACCINE – DECLINATION)

I understand that, due to my occupational exposure to blood or other potentially infectious materials, I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccine at this time. I understand that, by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me.

All of my questions regarding the risk of acquiring hepatitis B virus, and the hepatitis B virus vaccination process, have been answered to my satisfaction.

Employee's Name (printed) _____
Employee's signature _____
Employee ID no. _____
Date (mm/dd/yyyy)