



Biosafety Program

I. Policy

It is the policy of California State University, Fullerton (CSUF) to maintain, insofar as is reasonably possible, an environment that will not adversely affect the health, safety and well-being of students, employees, visitors and the surrounding community.

All research and teaching involving biohazardous materials will be conducted in conditions appropriate to the biosafety level (BSL) to protect the academic as areas and the greater campus community. All research involving infectious agents shall follow the guidelines prescribed in the Centers for Disease Control (CDC) and National Institutes of Health (NIH) publication Biosafety in Microbiological and Biomedical Laboratories (5th Ed., 2009) (BMBL). All research involving select agents and toxins shall follow the requirements prescribed in the University's Select Agent Program.

II. Authority

California Code of Regulations, Title 8, Section 5193

Biosafety in Microbiological and Biomedical Laboratories Fifth Edition, 2009, U. S. Dept. of Health and Human Services, Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH).

Medical Waste Management Act, California Health and Safety Code, Sections 117600-118360.

Select Agents Program, National Select Agents Registry

III. Scope

The program applies to all faculty, staff, students, contract employees and other personnel working at locations where CSUF has management control of biohazardous materials.

IV. Definitions

Animal Waste - Carcasses and body parts of preserved and unpreserved animals.

Biohazard bags - Red bags meeting ASTM standards for strength.

Biohazardous waste – Waste which includes:

- Laboratory waste that includes the cultures of infectious agents from research laboratories, wastes from the production of bacteria, and culture dishes and devices used to culture, transfer, inoculate and mix cultures of infectious agents.
- Human specimens.
- Animal parts suspected of infectious agents known to be contagious to humans.
- Human blood, blood products and their containers or equipment.

Biosafety levels - The levels of safety from exposure to infectious agents. They are a combination of practices, techniques, safety equipment and laboratory facilities required to isolate dangerous biological agents in an enclosed facility. The four levels of biosafety are summarized in Section VI.

Bloodborne Pathogens - 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 (HBP), hepatitis C virus (HVC) and human immunodeficiency virus (HIV).

Containment – A method of managing infectious agents in the laboratory environment where they are being handled or maintained. The purpose of containment is to reduce or eliminate exposure of laboratory personnel, other persons and the outside environment to potentially hazardous agents.

Primary containment - Involves the protection of personnel in the immediate laboratory environment from exposure to infectious agents, and is provided by good microbiological technique, the use of proper safety equipment and appropriate vaccines. Secondary containment refers to the protection of the environment external to the laboratory from exposure to infectious materials and is provided by a combination of facility design and operational practices.

Infectious agent - A type of microorganism, bacteria, mold, parasite or virus, including, but not limited to, organisms managed as Biosafety Level II-IV by the CDC that normally causes, or significantly contributes to the cause of, increased morbidity or mortality of human beings.

Institutional Biosafety Committee - Charged by Federal law with the planning and implementation of the campus Biosafety Program with a purpose to ensure the health and safety of all personnel working with biohazardous agents. Committee membership will be appointed by the Dean of Natural Science and Mathematics. The University Risk Manager and Biosafety Officer from Environmental Health and Safety will be standing members.

Medical Waste - Waste generated in the diagnosis, treatment or immunization of human beings or animals, or regulated waste as from a trauma scene. It also includes biohazardous waste or sharps waste (including personally generated waste such as syringe waste generated by persons who self-administer insulin for diabetes).

Medical Waste is NOT:

- Waste generated in biotechnology that does not contain human blood or blood products or animal blood or blood products suspected of being contaminated with infectious agents known to be communicable to humans.
- Urine, feces, saliva, sputum, nasal secretions, sweat, tears, or vomit, unless it contains fluid blood.
- Paper towels or articles containing dried blood.
- Hazardous, radioactive, or household waste.

Sharp - Any object used with infectious material that can be reasonably anticipated to penetrate the skin or any other part of the body, and to result in an exposure incident, including, but not limited to, needles, scalpels, lancets, broken glass, and broken capillary tubes. Sharps waste includes:

- Hypodermic needles with or without syringes.
- Syringes contaminated with biohazardous waste.
- Broken glass, such as Pasteur pipettes and blood vials contaminated with biohazardous waste.
- Any contaminated trauma scene waste capable of cutting or piercing.

Universal Precautions - A method of infection control by treating all human blood and certain human body fluids as infectious for HIV, HBV, HCV, and other bloodborne pathogens.

V. Accountability

A. Institutional Biosafety Committee

1. Establish policies and guidelines that meet or exceed applicable regulations for use of biohazardous materials conducted at or sponsored by CSUF.
2. Follow the National Institute of Health guidelines if the university engages in recombinant DNA research.
3. Review and approve proposed research activities that use biohazardous materials designated as BSL 2 or 3 or that is either exempt or non-exempt from NIH Recombinant DNA Guidelines. The review shall include an independent assessment of the containment required (practices, procedures, facilities and equipment used to safely manage biohazardous materials) and an assessment of the facilities, training and expertise of personnel involved in the research.
4. Oversee and review the use of potentially hazardous biological materials and Select Agents brought to the attention of the committee/
5. Develop a Biological Use Authorization form and procedures for PIs.
6. Meet as necessary.

B. Principal Investigator (PI)

The faculty member in whose assigned space a research activity is conducted. The PI performs and/or oversees activities that utilize or produce biohazardous materials. Responsibilities include:

1. Develop specific protocols to ensure the safe use of biohazardous materials and ensuring that all laboratory personnel comply with the specific safety protocols.
2. Determine the required levels of physical and biological containment, as well as appropriate microbiological practices and laboratory techniques.
3. Ensure that the containment equipment and facility requirements for activities performed under his/her direction meet the criteria for the appropriate BSL and certification standard.
4. Ensure that all maintenance in, on or around contaminated equipment is conducted only after that equipment is thoroughly decontaminated by the laboratory staff.
5. Develop specific protocols that outline proper emergency procedures for response to an accidental exposure of personnel or the environment to the biological agents and ensuring that all laboratory staff complies with the emergency procedures.
6. Submit a Biological Use Authorization, when applicable.
7. Obtain additional approvals, as appropriate, from the different committees relevant to the project - Institutional Animal Care and Use Committee (IACUC) when animals are used, Institutional Review Board (IRB) if human subject are involved, Radiation Safety Committee (RSC) if the project involves radioisotopes.
8. Comply with the specific federal, state, and local safety protocols and practices, as applicable.
9. Ensure that all laboratory staff under his/her supervision are appropriately trained on the safe use of biohazardous materials and enrolled in medical surveillance, if appropriate. Training and medical surveillance include animal care personnel not directly supervised by the PI who provide care for infected animals.
10. Comply with medical waste laws in the handling of medical waste in the laboratory and have access to an autoclave or an approved medical waste accumulation area.
11. Ensure that all laboratory staff, maintenance personnel and visitors who may be exposed to any biohazard are informed in advance of their potential risk and of the actions required to minimize that risk. In addition, the PI is

responsible for restricting access as required by the assigned biosafety containment level.

12. Report any significant problems, violations of the policies, practices and procedures set forth in this program, or any significant research- related accidents and/or laboratory-acquired infection to the Biosafety Committee and Environmental Health and Safety within 24 hours.
13. Comply with shipping requirements for biohazardous materials.

C. Qualified/Authorized Employees

1. Follow the laboratory's-specific biosafety practices and procedures.
2. Report immediately to the PI all problems, spills or violations in procedure. Report to the Biosafety Officer or Environmental Health and Safety any significant violations in biosafety policy, practices or procedures that are not resolved within a reasonable amount of time.
3. Know all emergency procedures established by the PI.

D. Biosafety Officer/Environmental Health and Safety (EHS)

1. Responsible for the development and implementation of the campus Biosafety Program.
2. Understand all applicable laws regulations. Develop guidelines pertaining to biosafety/biohazards.
3. Review proposed research or instructional activities involving the use of biohazardous materials and preparing recommendations to the Institutional Biosafety Committee.
4. Develop emergency plans for handling accidental spills and personnel contamination.
5. Investigate laboratory accidents involving biohazardous materials.
6. Develop and conduct training on biosafety issues, practices, and procedures.
7. Report to the Institutional Biosafety Committee any significant problems, violations of biosafety policy, practices or procedures and any significant research-related accidents or illnesses.
8. Conduct periodic hazard assessments and inspections to ensure that required laboratory practices and procedures are followed. Annual inspections will be conducted on all BSL1 labs; BSL2 labs will be inspected biannually.

9. Review biosafety facility construction/renovation plans and provide recommendations as necessary.
10. Dispose of biohazardous, medical, and animal waste.

VI. Program

A. Laboratory Biosafety Level Criteria

The following NIH guidelines will be used by all laboratory personnel and the Institutional Biosafety Committee to determine the proper practices, safety equipment and facilities applicable to the hazards present.

1. Biosafety Level 1 practices, safety equipment and facility design and construction are appropriate for undergraduate and secondary educational training and teaching laboratories and for other laboratories in which work is done with defined and characterized strains of viable microorganisms not known to consistently cause disease in healthy adult humans.
2. Biosafety Level 2 practices, equipment and facility design and construction are applicable to clinical, diagnostic, teaching and other facilities in which work is done with the broad spectrum of indigenous moderate-risk agents that are present in the community and associated with human disease of varying severity.
3. Biosafety Level 3 practices, equipment and facility design and construction are applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents where the potential for respiratory transmission, and which may cause serious or potentially lethal infection.
4. Biosafety Level 4 practices, equipment and facility design and construction are applicable to work with dangerous and exotic agents that pose a high individual risk of life-threatening disease, which may be transmitted via the aerosol route and for which there is no available vaccine or therapy.

Biosafety Level Summary

BSL	Agents	Practices and Techniques	Safety Equipment	Facilities
1	Not known to consistently cause disease in healthy adults	Standard microbiological practices, as detailed above.	None: primary containment provided by adherence to standard laboratory practices during open bench operations.	Open bench top and sink

BSL	Agents	Practices and Techniques	Safety Equipment	Facilities
2	Associated with human disease. Hazards include skin absorption, ingestion, mucous membrane exposure	BSL 1 practice plus: limited access, biohazard warning signs, sharps precautions, waste decontamination, medical surveillance	Primary containment = Class II BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials PPE: laboratory coats, gloves, face protection as needed	Basic BSL 1 plus: Autoclave available
3	Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences	BSL 2 practice plus: controlled access, decontamination of all waste, decontamination of lab clothing before laundering, baseline serum	Primary containment = Class II or III BSCs or other physical containment devices used for all open manipulations of agents. PPE: protective lab clothing, gloves, respiratory protection as needed	BSL 2 plus: Physical separation from access corridors. Self-closing, double-door access. Exhausted air not re-circulated. Negative airflow into laboratory.
4	Not currently permitted			

B. Handling Biological Materials

1. Biosafety Level 1 or higher

- a. The Principal Investigator or Lab Supervisor must enforce the policies of the Biosafety Program for his or her lab spaces and personnel (staff and students).
- b. Wear lab coat, gloves, closed toe shoes, and safety glasses to prevent contamination from biological entities, and remove them when leaving the work area.
- c. Employ Universal Precautions. This precaution were designed for working with bloodborne pathogens and is required for work with any Biosafety Level 2 and higher infectious agents, it is an excellent system to employ while working with any biological material.

- d. Decontaminate work surfaces with an approved sanitizer once per day and after any spill of viable material.
 - e. Use only mechanical pipetting devices; mouth pipetting is prohibited.
 - f. Eating, drinking and applying cosmetics are not permitted in the lab. Food must be stored in cabinets or refrigerators designated for this purpose and must be located outside the work area.
 - g. Wash hands after handling viable materials and animals and before leaving the lab.
 - h. A policy for the use the disposal of sharps in each laboratory must be developed and followed.
 - i. Perform all procedures carefully to minimize the creation of aerosols.
 - j. Transport biological materials in a labeled, leak-proof container. Infectious material must be placed in a red biohazard bag as well.
 - k. To eliminate finger sticks, recapping needles is forbidden.
2. Biosafety Level 2 or higher
- a. Limit access to areas where experiments with infectious agents are in progress.
 - b. Clearly label areas what infectious agent is in use or stored, and designate specific areas or equipment where those materials are routinely used, using this symbol (black on red background):



- c. Transport Infectious material materials in a labeled, leak-proof container that is placed inside a red biohazard bag.
- d. Individuals working with known infectious agents must be provided with medical surveillance, and offered appropriate immunizations when applicable.
- e. Incidents involving potential exposure must be reported immediately to the PI and Biosafety Officer/EHS.

C. Disposal of Biological Waste

1. Laboratory cultures include the biological agents (cells cultures, plants, algae, or other living entity) from research laboratories, wastes from their production, and culture dishes and devices used to culture, transfer, inoculate, and mix cultures.
 - a. All biologically active materials must be inactivated by autoclaving, UV light, germicidal agent, or any other proven effective method before disposal into the regular trash. *All waste must be rendered “environmentally neutral” before placing in the regular trash.*
 - b. All inactivated biological waste that is contained in bags that have a biohazard symbol MUST be placed in an opaque bag before disposal into the regular trash.
 - c. Unless otherwise established, inactivated waste will be taken directly to the regular trash bins by the user.
2. Animal Waste
 - a. Vertebrates or fish must be placed in clear plastic bags and frozen, when possible, and EHS called to arrange disposal.
 - b. Invertebrates must be placed in tightly closed plastic bags and taken directly to dumpsters outside the building. Avoid disposal on Fridays because trash will not be picked up until Monday.
 - c. Preserved animals and animal parts must be placed in plastic bags and EHS called for access to the carcass freezer. Any animal carcass or animal parts which have been preserved in formaldehyde or any other preservative must have as much of the preservatives leached from the carcass as possible and be drained completely of any fluids before they can be placed in any container for disposal. Notify EHS for pickup of the hazardous waste collected from the preserved specimens.
3. Medical Waste must be placed in red (labeled) “biohazard” bags and notify EHS for pickup.

Medical Waste is NOT:

 - a. Waste generated in biotechnology that does not contain an infectious agent or human blood or blood products.
 - b. Urine, feces, saliva, sputum, nasal secretions, sweat, tears, or vomit, unless it contains fluid blood.
 - c. Paper towels or articles containing non-fluid blood.

- d. Hazardous, radioactive or household waste, including home-generated sharps waste.
- 4. Sharps waste must be placed in red (labeled) “biohazard” plastic sharps container. Notify EHS before the container is filled.
- 5. Mixed waste is waste that has different categories of waste, such as biological waste mixed with chemicals or radioactive material. Use the following hierarchy to categorize the waste.
 - a. If biohazardous and radioactive:
 - i. Inactivate the biohazard, if possible. (Use procedures approved by the Radiation Safety Officer which restrict further contamination.) Classify as radioactive and treated accordingly.
 - ii. See Radiation Safety manual for treatment of radioactive materials.
 - b. If chemically hazardous and biohazardous:
 - i. Classify as chemically hazardous and treat accordingly.
 - ii. Call Chemical Hygiene Officer/EHS for specific instructions.
 - c. If biohazardous, chemically hazardous and radioactive:
 - i. Classify as radioactive and treated accordingly.
 - d. If chemically hazardous and radioactive (no biohazards present):
 - i. Contact Radiation Safety Officer/EHS for specific treatment for those radioactive materials and chemicals.
- 6. Disposal of Miscellaneous Biological Waste
 - a. Animal blood and body fluids – fresh, uninfected, untreated body fluids (USDA Grade, for example) must be disposed of in the laboratory garbage disposal, with copious amounts of water.
 - b. Human or animal urine – dispose of in the toilet or the laboratory drain with copious amounts of water; rinse the sink thoroughly with a 0.1% bleach solution.
 - c. Human cheek cells collected on swabs – dispose of in the normal trash.
- 7. Medical Waste Disposal Deadlines

Medical waste must be collected and shipped off campus either:

- a. Within 7 days, if stored at room temperature, or
- b. Within 90 days, if stored at or below 0 °C.
- c. EXCEPTION: Sealed sharps containers must be collected and shipped off campus within 7 days after deemed full, picked up by EHS, and placement in the Biohazard Waste Storage Container, regardless of storage temperature.

D. Autoclave Use for Biological Waste

An autoclave is an instrument used to sterilize equipment and supplies by subjecting them to high pressure saturated steam. It's also highly effective in treating biohazardous materials. Use the following guidelines to safely sterilize biological waster. For more information on autoclave, visit contact EHS.

1. Solid Waste

- a. Waste must be in an autoclave bag, with at least 200 ml of liquid.
- b. Bag must be vented to allow proper steam penetration.
- c. Bag should have a temperature indicator (e.g., autoclave tape).
- d. Bag must be placed in a metal pan to catch any leakage.
- e. Waste must be autoclaved for at least 45 minutes on LIQUID setting.
- f. Temperature must reach and be maintained at 250 °F. (121 °C) and pressure must be maintained at 15 lbs. for the entire autoclave time.
- g. Place autoclaved waste into blue trash bags (provided near the autoclaves), then taken directly to the dumpsters outside the building after they have cooled.

2. Liquid Waste

- a. Place containers of liquid waste in trays to collect any spilled material.
- b. Autoclave for 45 minutes on LIQUID setting.
- c. Dispose of liquid in lab sinks
- d. Strain out any solid material, place in plastic bags and take directly to the dumpsters.

E. Bloodborne Pathogens (BBP)

Bloodborne pathogens are pathogenic microorganisms that are transmitted via human blood and body fluids and cause disease in humans. They include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV). Although a number of pathogens can be transmitted percutaneously, HIV-1 remains the most common. For information on the campus Bloodborne Pathogen Program, please go contact EHS.

F. Select Agents

Select agents are biological agents and toxins which have been declared by the U.S. Department of Health and Human Services or by the U.S. Department of Agriculture to have the "potential to pose a severe threat to public health and safety." The Centers for Disease Control administers the Select Agent Program, which regulates the laboratories which may possess, use, or transfer select agents within the United States. A list of these materials can be found at www.selectagents.gov.

The university's Select Agent Program can be found on the EHS website.

G. Controlled Substances

Controlled substances are drugs or chemicals whose manufacture, possession, or uses are regulated by a government. This may include illegal drugs and prescription medications. A list of these substances can be found at www.deadiversion.usdoj.gov.

Environmental Health and Safety manages the Controlled Substances Program. For more information on the Controlled Substances Program contact EHS.

H. Hazard Communication

1. Signs shall be posted at the entrance to the work areas which shall bear:
 - a. Name of the infectious agent(s).
 - b. International symbol for biohazard in fluorescent orange-red.
 - c. Special requirements for entering the area.
 - d. Name and telephone number of the laboratory PI or other responsible person.
2. Warning labels shall be affixed to: containers of infectious waste; refrigerators and freezers containing blood and other potentially infectious materials; and other containers used to store or transport blood or other potentially infectious materials. Labels shall have the international biohazard symbol. The labels shall be fluorescent orange or orange-red with lettering or symbols in a contrasting color. The labels shall either be an integral part of the container or shall be tightly affixed to the container by adhesive to prevent their loss or removal.

I. Training

Individual supervisors and PIs, in consultation with EHS, shall ensure that all students and employees with potential for occupational exposure are trained in the proper techniques for handling and disposal of biohazardous materials. PIs and supervisors must ensure that students and employees are trained in and demonstrate proficiency in standard microbiological practices and in operations specific to the laboratory in question before being allowed to work with biohazards. Training should also include aspects of the Bloodborne Pathogen Program that would directly affect their specific laboratory work.

J. Emergency Procedures

Appropriate emergency procedures must be posted in all areas where biohazardous work occurs. In the event of any spill or contamination, immediately notify the PI or instructor and EHS.

1. Spills

- a. Notify personnel in the immediate area.
- b. Isolate the area to prevent the spread of contamination.
- c. Follow posted deactivation procedures.

2. Personnel Contamination

- a. Remove contaminated clothing
- b. Wash the exposed area with soap and rinse with water for 15 minutes. Use a safety shower or eyewash as necessary.
- c. Obtain medical attention, if necessary.

Responsible Executive: Vice President for Administration and Finance

Responsible Office: Environmental Health and Safety

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