

A. C.O.S.E. Biosafety Program

1. Biosafety Plan

The College of Science and Engineering (COSE) at San Francisco State University (the University) has developed this Biosafety Plan (Plan) for researchers, staff, and laboratory instructors who work with biological materials. It should be used in conjunction with the COSE Chemical Hygiene Plan, which covers chemical laboratory safety.

2. COSE Policy

- (1) COSE personnel are required to follow the protocols established in this Biosafety Plan (Plan) and to register biological materials that are potentially biohazardous.
- (2) Faculty and staff are expected to follow established Standard Microbiological Practices and to make sure safe work practices are carried out.
- (3) All biological wastes must either be disposed of using a licensed contractor or properly sterilized and packaged before placing in municipal trash bins.
- (4) Personnel who work with biological materials must be trained in their potential hazards and in appropriate protective measures as specified in this Plan.

3. Responsible Persons

- (1) The **Principal Investigator** is responsible for ensuring that all members of the laboratory are familiar with safe research practices.
- (2) **Staff technicians and lab managers** and others who provide supervisory roles in laboratory settings are responsible for overseeing the safety practices in their laboratories and for reporting problems or accidents to the appropriate faculty member or stockroom manager.
- (3) **Employees** who work with biological materials are responsible for reading this manual and/or attending a training session by their supervisor and for carrying out the safety practices outlined here.
- (4) **COSE Health and Safety staff** provides guidance, information, training, and review of biological safety programs as needed.
- (5) **Biosafety Committee** is responsible for reviewing the use of restricted or pathogenic biological materials.

4. Biosafety Committee (BSC)

The COSE has formed a Biosafety Committee (BSC) responsible for overseeing the use of potentially hazardous or restricted biological materials.

- (1) The BSC is made up of at least two staff members and two faculty members and chaired by one of the faculty.
- (2) The BSC must meet at least twice yearly to review biological materials applications and evaluate regulatory compliance.
- (3) The use of the following categories of biological agents must be reviewed by the BSC
 - ◀ US Patriot Act: Select Agents
 - ◀ Recombinant DNA
 - ◀ Pathogens of biological risk level 2 or above
- (4) Researchers and instructors who want to work with materials in the categories above must submit a “Biological Use Registration” (BUR) application to the BSC before such materials may be brought onto campus property.

5. Records

- (1) **Autoclave records**

Department personnel who are responsible for autoclaves must ensure QC and use logs are maintained and retained for at least 3 years:

 - ◀ Testing and maintenance logs
 - ◀ Use record logs each time waste is sterilized
 - ◀ Autoclave training records
- (2) **Training records**
 - ◀ Faculty and staff managers are responsible for keeping records of task/lab-specific training.
 - ◀ COSE Safety Staff keep records of Bloodborne Pathogen Training.
 - ◀ Safety training records are typically kept for three years, unless otherwise specified.
- (3) **Incident reports**

Lab managers are responsible for reporting incidents to the COSE Health and Safety Staff and for taking steps to prevent a recurrence.

 - ◀ Procedural or waste disposal non-compliance
 - ◀ Injury or illness
 - ◀ Security or access breaches
- (4) **HBV Immunization/Declination**
 - ◀ The Student Health Center keeps medical records,

including occupational exposure records.

- ◀ Campus EHOS keeps immunization declination forms and clearance documents on file.

6. Safety Training

Safety training for new employees is mandated by Title 8, CCR 3203, Injury and Illness Prevention Program and is the responsibility of the Principal Investigator or lab supervisor.

- (1) Train lab employees, including student volunteers, wherever biological organisms are used.
- (2) Include training for specific tasks and equipment.
- (3) Contact the Biology Stockroom Manager or COSE Health and Safety Staff for training materials or access the COSE Safety website at www.sfsu.edu/~safety.
- (4) Ensure that lab workers can show competence at their assigned tasks.
- (5) Review procedures when new organisms or materials are introduced.

7. Bloodborne Pathogen Prevention Program (BBP)

The presence of bloodborne pathogens in the workplace is regulated by Title 8 CCR 5193, Bloodborne Pathogens. This regulation covers medical clinics, teaching, and research laboratories working with HIV or HBV as well as other pathogenic organisms. Any use of human blood or other bodily fluids requires training in accordance with the BBP.

Campus EHOS maintains occupational monitoring and exposure records. Requests for hepatitis B vaccinations must be made to EHOS at x8-1449. The Student Health Center maintains confidential medical records. Please check the COSE Safety website to see the [University's Bloodborne Pathogens Prevention Program](#).

- (1) The targeted pathogens specifically include, but are not limited to, human immunodeficiency virus (HIV) and hepatitis B virus (HBV).
- (2) Report known or suspected contact with human bodily fluids, pathogens, and other potentially infectious materials to the EHOS Office (x8-1449) as soon as possible.
- (3) Medical and emergency personnel may opt to be immunized for HBV. The HBV vaccine is also available post-exposure following a medical evaluation.
- (4) Use **Universal Precautions**: Treat all bodily fluids, animals parts, and other potentially contaminated materials as if they were contaminated with a pathogen or infectious material.

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B. Biological Risk Groups

1. Safety and Biological Risk Groups

Biological agents, plant or animal, are classified according to biosafety level risk groups. These classifications presume ordinary circumstances in the research laboratory or growth of agents in small volumes for diagnostic and experimental purposes.

Infectious organisms are categorized in groups based on relative risk taking the following factors into consideration:

- ◀ Pathogenicity
- ◀ Mode of transmission and host range
- ◀ Availability of effective preventive measures (*e.g.*, vaccines)
- ◀ Availability of effective treatment (*e.g.*, antibiotics)

BSL-1 risk group contains biological agents that pose low risk to personnel and the environment. These agents are highly unlikely to cause disease in healthy laboratory workers, animals or plants. The agents require Biosafety Level 1 containment.

BSL-2 risk group contains biological agents that pose moderate risk to personnel and the environment. If exposure occurs in a laboratory situation, the risk of spread is limited and rarely would cause infection that would lead to serious disease. Effective treatment and preventive measures are available in the event that an infection occurs. The agents require Biosafety Level 2 containment. **REGISTRATION REQUIRED**

BSL-3 risk group contains biological agents that usually cause serious disease (human, animal or plant) or that can result in serious economic consequences. These agents are usually not spread by casual contact. The agents require Biosafety Level 3 containment. **RESTRICTED-NEW FACILITIES REQUIRED.**

BSL-4 risk group contains biological agents that usually produce very serious disease (human, animal or plant) that is often untreatable. These agents are usually easily transmitted from one individual to another, from animal to human or vice-versa, either directly or indirectly, or by casual contact. The agents require Biosafety Level 4 containment. **PROHIBITED ON CAMPUS**

2. Recombinant DNA

Recombinant DNA (rDNA) work must first be formally reviewed by the BSC — including activities that are “exempt” per the NIH Guidelines. Work with rDNA requires the researcher to fill out the Biosafety Use Registration application.

Work must meet published NIH guidelines for rDNA:
<http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>

3. Select Agents

Use of organisms listed under the U.S. Patriot Act as “**Select Agents**” is severely restricted.

- ◀ A written request justifying the need to use such materials must be submitted to the Department Chair for initial approval then forwarded to either the COSE Health and Safety Specialist or BSC Chair.
- ◀ Both the BSC Chair and SFSU’s “Responsible Person” (Campus EHOS Director) must approve the request and the proposed plan for meeting the extensive security and oversight requirements.
- ◀ The appropriate safeguards and facilities must be in place

For more information and a current list of Select Agents, visit the CDC web site: <http://www.cdc.gov/od/sap/docs/salist.pdf>

4. Animal Subjects

Research using live animals is performed under the oversight of the University’s Office for the Protection of Human and Animal Subjects. No research with live animals may be conducted without the approval of their Institutional Review Board (IRB). For more information, go to their website:

<http://www.sfsu.edu/~protocol/human/review-required.htmls> .

5. Human Subjects

Research using human beings or human cell cultures, organs, etc., is performed under the oversight of the University’s Office for the Protection of Human and Animal Subjects. No research with live animals or humans may be conducted without IRB approval. Some types of research do not require IRB review and exemptions are available for certain situations. For more information about the University’s policies, go to their website:

<http://www.sfsu.edu/~protocol/human/review-required.htmls> .

6. Biosafety Level Criteria

A **Biosafety Level** (BSL) is the level of the *biocontainment* precautions required to isolate potentially dangerous biological agents in an enclosed facility. The levels of containment range from the lowest biosafety level 1 to the highest at level 4. In the United States, the Centers for Disease Control and Prevention (CDC) have specified these levels.

The College of Science & Engineering has adopted the definitions and recommended practices for the levels of risk established in Section III in the document entitled: “**CDC/NIH: Biosafety in Microbiological and Biomedical Laboratories.**”^{* 4th Ed. 1999.}

6. Biosafety Level Criteria (continued)

A summary of the biosafety level categories and associated safe work practices and facility requirements can be found in **Table 1**

(BSL-1) Biosafety Level 1 is suitable for work involving well-characterized agents not known to consistently cause disease in healthy adult humans, and of minimal potential hazard to laboratory personnel and the environment. Work is generally conducted on open bench tops using standard microbiological practices.

(BSL-2) Biosafety Level 2 (BSL-2) is similar to **BSL- 1** and is suitable for work involving agents of moderate potential hazard to personnel and the environment. It differs from Level 1 in that workers must have specific training in handling pathogenic agents and some controls are now required.

- ◀ Work must be done in a biosafety cabinet if aerosols are being generated
- ◀ Keep an accurate inventory and limit access to trained and authorized people.
- ◀ Advise pregnant women or immuno-compromised people who enter the laboratory of the associated risks.
- ◀ Post a hazard warning sign indicating the risk level of the organism(s) being used outside each entrance to the work area.

(BSL-3) Biosafety Level 3 is applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents that may cause serious or potentially lethal disease as a result of exposure by the inhalation route. In addition to BSL-2 practices, strict controls are required that are, in general, beyond what the COSE can normally provide without significant laboratory redesign:

- ◀ All work must be done in a biosafety cabinet whether or not aerosols are generated.
- ◀ Isolate and/or secure areas where Level 3 organisms are handled or stored.
- ◀ Gloves and protective eyewear must be worn for all procedures that might involve direct skin or eye contact with toxins, bodily fluids, infectious materials, or infectious animals

(BSL-4) Biosafety Level 4 is required for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease. Using Level 4 agents for research is severely restricted due to the limitations of COSE facilities and controls of government regulations such as the US Patriot Act.

Researchers will be required to make arrangements with off-site laboratories equipped to handle such organisms.

Table 1. Summary of Recommended Biosafety Levels for Infectious Agents

BSL	Agents	Practices	Safety Equipment	Facilities
1	Not known to consistently cause disease in healthy adults	Standard microbiological practices.	None required.	Open bench top sink required.
2	Associated with human disease, percutaneous injury, ingestion, mucous membrane exposure	BSL-1 practice plus: <ul style="list-style-type: none"> • Limited access • Biohazard warning signs • ‘Sharps’ precautions • Biosafety manual defining any necessary waste decontamination or medical surveillance policies 	Primary barriers: Class I or Class II Biological Safety Cabinets or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials PPE: lab coats, gloves, face protection as needed	BSL-1 plus <ul style="list-style-type: none"> • Available autoclave
3	Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences	BSL-2 practice plus: <ul style="list-style-type: none"> • Controlled access • Decontamination of all waste • Decontamination of lab clothing before laundering • Baseline serum 	Primary Barriers: Class I or Class II biological safety cabinets or other physical containment devices used for all open manipulations of agents. PPE: Lab coats, gloves, respiratory protection as needed, face protection as needed, additional protective clothing as needed	BSL-2 plus: <ul style="list-style-type: none"> • Physical separation from access corridors • Self-closing, double-door access • Exhausted air is not re-circulated • Negative airflow into laboratory
4	Dangerous/exotic agents which pose high risk of life-threatening disease, aerosol-transmitted lab infections; or related agents with unknown risk of transmission	BSL-3 practice plus: <ul style="list-style-type: none"> • Clothing change before entering • Shower on exit • All material decontaminated upon exit from facility 	Primary Barriers: All procedures conducted in Class III biological safety cabinets or Class I or Class II biological safety cabinets IN COMBINATION WITH full-body, air supplied, positive pressure personnel suit.	BSL-3 plus: <ul style="list-style-type: none"> • Separate building or isolated zone • Dedicated supply and exhaust, vacuum, and decontamination equipment

C. Standard Microbiological Practices

Standard Microbiological Practices refer to the basic safe laboratory work protocols for working with non-pathogenic biological materials (i.e., **Biosafety Level 1**). Laboratory personnel must have specific training in the procedures conducted in the laboratory. A qualified faculty or staff person must provide this training and provide sufficient supervision to adequately operate a safe and compliant laboratory.

Work is generally conducted on open bench tops using the following standard microbiological practices.

1. Hygiene and Housekeeping

Keeping work areas clean and uncluttered reduces the chance for cross-contamination and inadvertent exposure to biohazards. To avoid ingestion of contaminated material, use a mechanical pipetting device, keep food out of refrigerators and microwaves in work areas, eat, drink, or apply cosmetics only in designated “clean” areas. Other standard practices include:

- (1) Wear a lab coat and tie back long hair
- (2) Wash hands after removing gloves, before leaving the lab, and when handling materials known or suspected to be contaminated.
- (3) Perform procedures in a manner that minimizes the creation of aerosols.
- (4) Clean work surfaces and decontaminate with a suitable disinfectant at the end of the day and after any spill of potentially hazardous materials.
- (5) Bench tops and floors should be impervious to water and easy to clean.
- (6) Remove gloves before leaving the lab, touching the face, keyboards, or control panels, and before using the elevator

2. Personal Protective Equipment

Wear gloves if skin on the hand is broken, if a rash is present, and when handling biological waste.

Remove rings or other jewelry that could puncture gloves.

Wear the appropriate glove for the hazard. Usually a type of latex glove is recommended for working with biological material.

Avoid reusing gloves unless they can be decontaminated.

Wear eyewear approved for UV light or other rays that could damage eyes.

Wear protective eyewear during procedures in which splashes of microorganisms or other hazardous materials is anticipated.

3. Security and Access

Access to the laboratory should be restricted at the discretion of the laboratory manager when experiments or work with cultures and specimens are in progress. Biohazardous material must be clearly marked with a biohazard symbol.

D. Biological Waste

Biological waste is handled differently from chemically contaminated waste. This section summarizes the campus policy on handling biological waste. Biohazardous waste handling is strictly regulated by the State of California through the California Medical Waste Management Act (California H&S Code Div. 20, Chapter 6.1, Sections 117600 – 118360).

1. Disposal Policy

As small generators of biohazardous waste, the departments of Biology and Biochemistry are permitted to sterilize and dispose of their own waste using standard protocols.

See **Table 2** for a summary of the different waste types and their respective disposal methods.

All microbiological and biohazardous materials must be sterilized before disposal **except**: sharps containers, fluid blood, animal parts, organic solvents, and human waste.

Biohazard bags and containers must be orange/red, used only for biological waste, and never recycled. Autoclaving indicator tape or special bag with intrinsic indicator is required.

Licensed contractors pick up the following biological wastes from the rooms where they are generated. Contact the Biology Stockroom at x8-1091 for pickup.

- ◀ Human waste from the anatomy lab
- ◀ Research animals and tissues
- ◀ Medical waste such as human blood and other bodily fluids

Sharps waste, such as broken glass and needles, must be separated according to the type of contamination and the containers must be closed, taped shut, and appropriately labeled. Contact the Biology Stockroom for disposal and refer to Appendix B for more detailed procedures concerning sharps.

2. Autoclaving Waste

Autoclaved waste has been sterilized with a combination of heat and pressure so may be safely disposed of in the regular trash when this policy is carefully followed.

It is the policy of COSE that most biological waste materials must be autoclaved or otherwise sterilized before they may be disposed of — whether confirmed to be infectious or not. Note, however, that not all biological materials may be autoclaved.

Biological waste that **MUST** be autoclaved before disposal:

- ◀ Human or animal culture specimens from medical or pathology labs.
- ◀ Cultures and stocks of microorganisms from research and instructional labs.
- ◀ Waste from the production of bacteria, viruses, or use of spores.

2. Autoclaving Waste

(continued)

- (1) Biological waste that **MUST** be autoclaved before disposal:
- ◀ Live and attenuated vaccines used in research animal vaccines.
 - ◀ Culture dishes and devices used to transfer, inoculate, and/or mix cultures.
 - ◀ Waste containing any microbiological specimens or cultures.

Biological waste that may **NOT** be autoclaved and must be disposed of by alternate means:

- ◀ Human body parts or tissues
- ◀ Liquid Blood
- ◀ Animal Carcasses or body parts
- ◀ Sharps
- ◀ Organic Solvents

If your waste type is not on this list, contact the BIS Facility at 8-2288 or Biology Stockroom x8-1091 for instructions.

3. Autoclave Use Policy

Autoclave users must be trained *before* using these machines. Contact BIS Facility at x8-2288.

The guidelines for using the autoclave must be posted or available at each location.

- ◀ Biology Dept. autoclaves: HH530, 405, 617, and BIS Facility (HH 632)
- ◀ Chemistry Dept. autoclaves: TH 629, 814, 815

Biohazard bags and other biological waste containers must be of the type suitable for autoclaving.

The generator is responsible for legibly noting the following information on each bag using permanent ink that can withstand autoclave temperatures.

- ◀ Name of the laboratory;
- ◀ Date the bag was autoclaved;
- ◀ Room number where the waste was generated;
- ◀ Telephone extension

The person autoclaving the material must place a strip of autoclave tape at least 6 inches long across the biohazard symbol on the autoclave bag or container.

Sterilization must be confirmed before disposal. To confirm sterilization, check to make sure the indicator tape (or indicator on bag) has changed color or pattern.

- (7) Once sterilization is confirmed, the waste must be placed into heavy-duty (≥ 1.3 mil thickness) opaque plastic bags then disposed of in the municipal trash.

The autoclaved bags and their contents must be rendered "unrecognizable" as a consideration to custodial staff and the public.

4. Biochemistry Sterilization Policy

- (1) Waste from liquid cell cultures is typically bleached before disposal
- (2) The following materials (if contaminated) are sterilized using the autoclave before disposal or re-use:
 - ◀ Liquid growth media
 - ◀ Buffers and water
 - ◀ Cell waste (*agar plates with bacterial plated on them, bacterial cell pellet, mammalian cell cultures, pipets and microplates contaminated with bacteria or mammalian cells*)
 - ◀ Disposable inoculation loops
 - ◀ Plastics (*pipet tips, tubes*)
 - ◀ Glass (*bottles, flasks, pipets*)

5. Animal Waste Policy

Animal care and waste disposal is governed by the SFSU's Institutional Animal Care and Use Committee. Below is a brief overview of the protocol for disposing of animal waste.

- (1) Notify the Animal Care Coordinator at x8-6336 when animal carcasses and associated animal wastes are ready for disposal. SFSU Animal Facilities uses a licensed waste hauler to remove and incinerate all animal material.
- (2) Used animal bedding and materials may be placed into municipal trash after securely wrapping in plastic bag at least 2 milspec thick. If contaminated with blood or other fluids, must be treated as biohazardous waste.
- (3) Lab personnel must take animal remains to the temporary storage freezer and wrap remains in plastic bags (should be available in the room).
- (4) Fill out the freezer log with the information below each time:
 - ◀ Date
 - ◀ Name of principal investigator
 - ◀ Type of animal waste and amount of each type
- (5) Attach one of the Animal Facilities identification labels on the bag. If one is not available, contact the Animal Care Coordinator and put a label on the bag with the following information:
 - ◀ Name of principal investigator
 - ◀ Building and room number of PI
 - ◀ Telephone number
 - ◀ Protocol number
 - ◀ Type of animal waste and amount of each type
- (6) Personnel must put preserved waste materials into a storage drum as directed by the Animal Care Coordinator.

6. Human Waste Policy

- (1) Anatomy lab cadavers and body parts are disposed of using a licensed contractor under the auspices of the Biology Stockroom.
- (2) Human blood (in liquid form) is considered medical waste and must be disposed of through a licensed contractor. Contact the Biology Stockroom for assistance in disposal of human blood and other bodily fluids.

Table 2. Summary of biological waste and disposal

Waste Category	Examples	Treatment and Disposal
<p>Liquid human and animal waste Blood, blood products, body fluids <u>Not including</u> urine or materials stained with blood or body fluids</p>	<p>Student blood Animal blood</p>	<p>Store and package in place Contact stockroom for pickup Waste transportation and disposal by licensed contractor (Not autoclavable)</p>
<p>Pathological Waste Human cadavers Animal Carcasses</p>	<p>Sacrificed animals and parts All human tissues Animal tissues associated with infectious disease or rDNA</p>	<p>Store and package in place Contact stockroom for pickup Waste transportation and disposal by licensed contractor (Not autoclavable)</p>
<p>Medical Sharps Used during work with humans or animals Potentially pathogenic or infectious</p>	<p>Needles Syringes with or without needles attached Scalpels</p>	<p>Collect in approved red sharps container Bring to stockroom when no more than ¾ full (Not autoclavable)</p>
<p>Standard Sharps Not contaminated Contaminated with biological materials that are not pathogenic</p>	<p>Pasteur pipettes Slides Broken glassware</p>	<p>Collect uncontaminated broken glassware, etc. in a cardboard box, label, and tape closed. Collect contaminated sharps as for medical sharps (Not autoclavable)</p>
<p>Solid Waste (non-sharp) Solid objects, no liquids Contaminated with biological materials that are not pathogenic</p>	<p>Gloves Paper towels Culture or blood tubes Plasticware i.e., culture plates, specimen vials, pipette tips</p>	<p>Collect in an autoclavable biohazard bag Sterilize with autoclave as directed Once properly packaged, may be disposed of in municipal trash. (Autoclavable)</p>
<p>“Mixed” Biological Waste <i>Material with one or more hazardous components other than biohazards.</i></p>	<p>Alcohol/biological mixtures Formalin/tissue mixtures Radioisotope marked cell cultures or microbes <i>(May not be autoclavable—please check first)</i></p>	<p>Contact COSE Health and Safety staff for assistance in handling mixed hazard wastes. Organic solvents are not autoclavable (Not autoclavable) Radioactive waste must be handled by the RSO</p>