Biosafety Program Manual





San Francisco State University Update: January 2024

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A. Biosafety Program

San Francisco State University (the University) has developed this Biosafety Program Manual (Manual) for researchers, staff, and laboratory instructors who work with biological materials. It should be used in conjunction with the Chemical Hygiene and Safety Plan, which covers chemical laboratory safety.

1.0 Scope of the Biosafety Program

The Biosafety Program covers departments and facilities associated with the University, including the Romberg Tiburon Center and field station operations under the control of SFSU. The biosafety program described in this Manual covers biological work in the sciences.

2.0 Expectations

This Manual serves as a blueprint for scientific work with biologicals, particularly those that are pathogenic to humans, plants, animals, or the environment.

- (1) SFSU personnel are required to follow the protocols established in this Biosafety Program Manual 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. Certain liquid wastes may be disinfected before disposal into the municipal sewer system using a bleach solution or other approved solution.
- (4) Personnel who work with biological materials must be trained in their potential hazards and in appropriate protective measures as specified in this Manual.
- (5) People with immune systems that are compromised due to pregnancy or other health conditions, should consult with their personal physician to assess their risks. Special accommodation may be possible in certain situations. Contact campus DPRC (Disability Programs and Resource Center) for more information. Email Phone: 415.338.2472

3.0 Personnel Responsibilities

Each person working with biological materials in the sciences are responsible for following, at a minimum, the Standard Microbiological Practices listed in **SECTION C**, of this Manual.

- (1) The Principal Investigator is responsible for ensuring that all members of the laboratory are familiar with safe research practices and to have appropriate personal protective equipment available.
- (2) Staff technicians, instructors, 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) Faculty and staff in supervisory roles are also responsible for ensuring compliance with other aspects of the Biosafety Program.
 - Completing the Biohazard Use Authorization process when applicable to the materials to be used
 - Understanding the risk classification of their biological agents
 - Storing and disposing of biological waste in accordance with Section E of this manual
- (4) 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.
- (5) Campus EH&S staff provides guidance, information, training, and review of biological safety programs as needed.
- (6) Biosafety Committee is responsible for reviewing the use of restricted or pathogenic biological materials.

4.0 University Biosafety Committee

SFSU has formed a Biosafety Committee (BSC) responsible for overseeing the use of biological materials in the sciences, especially the use of biohazardous materials or organisms.

- (1) The BSC is made up of at least two staff members and two faculty members and chaired by one of the faculty in the sciences.
- (2) The BSC will meet periodically to review biological materials applications and evaluate regulatory compliance as necessary
- (3) The use of the following categories of biological agents must be reviewed by the BSC
 - US Patriot Act: Select Agents
 - Recombinant DNA and RSNA work
 - Pathogens of Risk Group 2 or above
 - Some uses of Risk Group 1 biological materials
- (4) Researchers and instructors who want to work with materials in the categories above must submit a "Biohazard Use Authorization" (BUA) application to the BSC before such materials may be brought onto campus property.

The University Biosafety Committee is not an Institutional Biosafety Committee (IBC) as described by NIH (National Institutes of Health and CDC (Centers for Disease Control). At this time, all BSL-3, BSL-4, and most NIH "non-exempt" RSNA projects are not approved for use at SFSU. Exception: The BSC has approved the use of **E. Coli B** and **W** strain, which is NIH non-exempt. *In certain cases, non-exempt RSNA projects may be approved by the ORSP Administration in consultation with the Biosafety Committee.*



5.0 Records

Recordkeeping is an essential part of the SFSU Biosafety Program.

- (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
 - Record use in log books 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.
 - Campus EH&S Staff keep records of Bloodborne Pathogen Training. Refresher training is done online or via in-person classroom sessions.
 - The Biology Dept manages user training for the *Biology autoclaves* used to treat waste. Annual refresher training is available online.
 - Safety training records are typically kept for three years, unless otherwise specified.
- (3) Incident reports

Lab managers are responsible for reporting incidents to the Campus EH&S Staff and for taking steps to prevent recurrences. Incidents resulting in injuries requiring treatment must be reported to ERM-Worker's Compensation group at 415.338.2565.

6.0 Employee 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 staff supervisor.

- (1) Train lab employees, including student volunteers, wherever biological organisms are used in good microbiological use practices.
- (2) Include training for specific tasks and equipment.
- (3) Document training in BSL-2 safe work practices for affected workers. A training course is available online.
- (4) Ensure that lab workers can show competence at their assigned tasks.
- (5) Review procedures when new organisms or materials are introduced.

7.0 Biohazardous Waste

The Campus Environment, Health, and Safety department ("Campus EH&S") oversees the campus Medical Waste Management Plan (MWMP). BSL-2 biohazardous waste is "medical waste" per the California Medical Waste Management Act (MWMA) and is regulated accordingly. *Section E* of this Manual describes the requirements for storing, treating, and disposing of biological waste.



8.0 Bloodborne Pathogens

The presence of bloodborne pathogens in the workplace is regulated by Title 8 CCR 5193, Bloodborne Pathogens Standard (BBP). This regulation applies medical clinics, teaching, and research laboratories working with blood and other materials that could contain human pathogens, such as HIV.

Note: Other employee groups such as uniformed police officers and custodians with occupational exposure to human blood or other potentially infectious materials are also covered by the BBP Standard, but are beyond the scope of this program.

Any use of human blood or unfixed tissue, or work with human pathogens falls under the campus **BBP Exposure Control Plan**. The University Biosafety Committee (BSC) requires a BBP Work-specific Exposure Control Plan be submitted as part of the BUA application.

9.0 Aerosol Transmissible Diseases

The California Occupational Safety and Health Administration (Cal/OSHA) issued the Aerosol Transmissible Diseases Standard to mitigate occupational exposures to pathogens transmitted via aerosols and droplets. The regulations specify that employers must implement an effective program to minimize exposure of employees to aerosol transmitted diseases (ATD). Certain laboratory operations are subject the ATD standard as specified in 8 CCR 5199(f): *Laboratories*.

At SF State, laboratories that use one or more of the agents or organisms listed in <u>8 CCR 5199</u>, <u>Appendix D</u> are subject to additional requirements. Agents listed include *Salmonella* spp.

BSL-2 organisms listed in the ATD Standard, are designated as BSL-2* in the SFSU Biosafety Program.

The <u>ATD Biosafety and Exposure Control Plan for Laboratories</u>, included as Appendix C of this document, is intended to fulfill the requirements as specified by the ATD Standard. Contact <u>EH&S Office</u> for more information.

A separate section, § 5199.1 Aerosol Transmissible Diseases - Zoonotic), explicitly covers operations involving the capture, sampling, or transportation of wildlife and operations involving samples, cultures, or other materials potentially containing zoonotic aerosol transmissible pathogens. Contact the IACUC, Institutional Animal Care and Use Committee, for more information.

10.0 Immune Competence and Susceptibility

Personal health status may affect an individual's susceptibility to infections and ability to receive available immunizations or prophylactic interventions. As part of initial safety training concerning specific laboratory hazards and work with biological materials, the lab supervisor should review the risk of susceptibility to infectious agents. Pregnant persons and those with compromised immune systems should discuss their situation with their personal medical

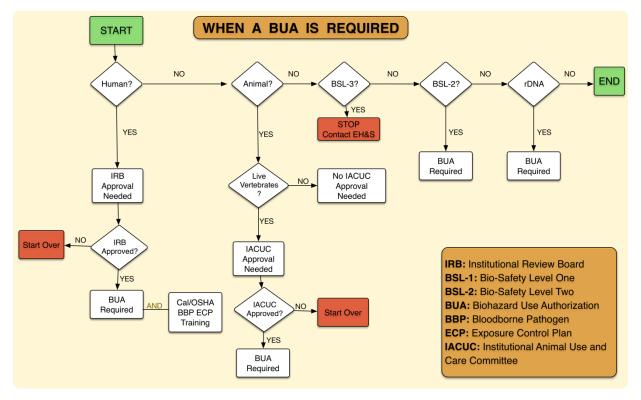


provider. Personnel with compromised immune systems will not be asked to identify themselves.

Examples of persons with weakened immune systems include those with AIDS; cancer and transplant patients who are taking certain immunosuppressive drugs; and those with inherited diseases that affect the immune system (e.g., congenital agammaglobulinemia, congenital IgA deficiency). The risk of developing severe disease may differ depending on each person's degree of immune suppression.

11.0 Biohazard Use Authorizations

The Biohazard Use Authorization or BUA is the cornerstone of managing work with potentially biohazardous microbes and other materials. An approved BUA is required before research or teaching activities involving this material may begin.



For details on how to submit a BUA application, see the **Application Instructions for Authorization to Use Biohazardous Materials**. (link to EH&S web page pending.)

Bringing Biohazards onto Campus Property

Faculty, staff, lecturers, students, and visiting scholars who plan to bring, use, or store biohazardous materials or work with human blood or tissues must get approval from the Biosafety Committee (BSC)—before bringing them to campus. This is done by submitting a Biohazard Use Authorization (BUA) application to EH&S who will then distribute to the BSC.



Laboratory classes and research that use biohazardous materials are required to operate under an approved BUA

- (1) At least one Biosafety Committee member will review the BUA application and advise the BSC if the material may be used or added to the curriculum.
- (2) Security of the materials, training lab personnel, reviewing hazards with the students and posting the presence of these materials is required per BSL-2 protocols. See page 8.

NOTE: There are no exceptions to this requirement.



B. Biological Risk Groups

Biological agents are classified according to biohazard 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., antibiotic)

All work with biological materials requires a risk assessment to determine the appropriate biosafety level practices.

1.0 Biosafety Levels of Containment

Biosafety Level (BSL) is the level of the bio-containment precautions required to contain 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) and National Institutes of Health (NIH) have specified these levels in their publication, "<u>Biosafety in Microbiological and Biomedical Laboratories</u>."* 6th Ed. 2020, known as BMBL.

SFSU has adopted the definitions and recommended practices for the levels of risk established in Section III of the BMBL manual. Some of the recommended practices are listed here. Review the BMBL for the full list.

(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 typically conducted on open bench tops using standard microbiological practices. Examples:

- And washing, safe use of "sharps", no food in lab
- decontamination of surfaces after completion of work
- Facility: Plumbed sink for hand washing
- **PPE:** lab coat, gloves, safety glasses.

No BUA is required unless work with recombinant or synthetic nucleic acid molecules (RSNA) or other recombinant gene work is being done.



(BSL-2)

Biosafety Level 2 (BSL-2) work involves agents of moderate potential hazard to personnel and the environment. It differs from BSL-1 in that workers must have specific training in handling pathogenic agents and more controls are now required. The laboratory manager or principal investigator is required follow the practices below:

- (1) Perform work in a biosafety cabinet if aerosols are being generated. Below are some tasks that can generate aerosols:
 - Grinding, Blending
 - Shaking, Mixing
 - Sonicating
 - Opening containers of infectious materials
 - Harvesting infected tissues from animals or eggs
- (2) Keep an accurate inventory and limit access to trained and authorized people.
- (3) Provide information regarding immune competence and susceptibility to infectious agents. Personal health status may affect an individual's susceptibility to infection and ability to receive available immunizations or prophylactic interventions. associated risks.
- (4) Post a hazard warning sign indicating the risk level of the organism(s) being used outside each entrance to the work area.
 - Facility: Available biosafety cabinet, handwashing station, lockable doors
 - PPE: lab coat, gloves, eye protection

An approved Biohazard Use Authorization is required.

(BSL-2*) Biosafety Level 2 star designation is for risk level 2 agents that are specifically mentioned in Cal/OSHA ATD standard. Biosafety Level practices are expected but special consideration to the generation of aerosols in accordance with the SFSU Laboratory Aerosol Diseases Plan included in Appendix C of this program manual.

(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 University can normally provide without significant laboratory redesign. Some examples are listed below:

- (1) All work must be done in a biosafety cabinet, whether or not aerosols are generated.
- (2) Isolate and/or secure areas where BSL-3 organisms are handled or stored. Physical separation from access corridors is required.
- (3) Self-closing doors and double-door access installed.
- (4) Exhausted air is not recirculated. Negative pressure in lab.



Work requiring BSL-3 containment cannot be accommodated at SFSU. The researcher must arrange to do this work elsewhere.

(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.

Work requiring BSL-4 containment cannot be accommodated at SFSU Researchers must make arrangements with off-site laboratories equipped to handle such organisms.

2.0 Recombinant or Synthetic Nucleic Acid Molecules (RSNA)

RSNA, formerly known as rDNA, work must first be reviewed by the University Biosafety Committee (BSC)— including activities that are "exempt" per NIH Guidelines and/or require only BSL-1 controls.

Work with RSNA material requires the researcher or applicant to fill out an RSNA Registration Form. The University Biosafety Committee (BSC) will determine whether a t Biosafety Use Authorization is required. RSNA work on campus may require either BSL-1 or BSL-2 containment depending on the information provided on the Registration form.

The applicant is responsible for doing a risk assessment as outlined below:

- Primary risk assessment factors
 - Agent hazards
 - Laboratory procedure hazards
 - · Capability of lab staff to control hazards
 - Operational integrity of containment equipment
 - Facility safeguards
- Agent hazards
 - Look up the Risk Group category for the agent(s) used
 - Determine what other risks the agent has

Laboratory procedure hazard

· Generation of aerosols, complicated procedures, use of sharps

Work must meet the requirements published in NIH Guidelines for Research Involving RSNA

3.0 Select Agents

The Federal Select Agent Program oversees the possession, use and transfer of biological Select Agents and toxins, which have the potential to pose a severe threat to public, animal or plant health or to animal or plant products.

(1) Use of organisms listed under the U.S. Patriot Act, as "Select Agents" is severely restricted.

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- (2) A written request justifying the need to use such materials must be submitted to the Department Chair for initial approval. Once approved, the request can then be forwarded to campus <u>EH&S Dept</u> via email.
 - Use of Select Agents requires background checks and special security protocols.
 - All such work must meet the requirements of the U.S. Patriot Act. The applicant is responsible for providing the proposed plan along with the written request.

For more information and a current list of Select Agents, visit the CDC Division of Select Agents and Toxins web site

4.0 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 the Institutional Animal Care and Use Committee (IACUC). For more information, go to the <u>IACUC website</u>.

The University Biosafety Committee will review the use of live animals from the perspective of facilities and biohazards related to infectious or potentially pathogenic materials. An approved BUA is required in addition to IACUC approval.

5.0 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 using humans, unfixed human tissue, blood, etc. maybe conducted without Institutional Review Board (IRB) approval. Some types of research do not require full IRB review and such determination will be made as part of the application process. For more information about the University's policies, go to the <u>IRB website</u>.



C. Standard Microbiological Practices

Standard Microbiological Practices refer to the basic safe laboratory work protocols for working with biological materials. This section summarizes the practices described in the CDC/NIH BMBL Manual, so is not a complete list of practices.

Laboratory personnel must have specific training in the procedures conducted in the laboratory. For BSL-2 work, a qualified faculty or staff person must provide this training and provide sufficient supervision to adequately operate a safe and compliant laboratory.

1.0 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

2.0 Personal Protective Equipment (PPE)

- (1) Wear gloves when handling biological materials or touching work areas where they are used. Cover any cuts, scrapes, rashes, broken skin with a waterproof covering prior to putting on laboratory gloves.
- (2) Remove rings or other jewelry that could puncture gloves.
- (3) Wear the appropriate glove for the hazard.
- (4) Do not reuse disposable gloves.
- (5) Wear protective eyewear in laboratories as specified by the risk assessment. Tasks that can expose the eyes to UV light or lasers requires specially designed eyewear.

3.0 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.



D. Biosafety Level 2 Containment Practices

Good Microbiological Techniques, using World Health Organization (WHO) terminology, refer to the practices and procedures that are fundamental for safe laboratory operations. Specialized laboratory equipment is a supplement to but can never replace appropriate procedures. The containment practices below are in addition to the standard microbiological practices described above in **SECTION C**.

1.0 Access

- (1) The international biohazard warning symbol and sign (Figure 1) must be displayed on the doors of the rooms where microorganisms of Risk Group 2 or higher risk groups are handled.
- (2) Only authorized persons should be allowed to enter the laboratory working areas.
- (3) Laboratory doors should be kept closed.
- (4) Minors should not be authorized or allowed to enter laboratory working areas.
- (5) Access to animal facility should be specially authorized.
- (6) No animals should be admitted other than those involved in the work of the laboratory. Contact DPRC to make arrangements for those requiring service animals.

2.0 Personal Protection & Clothing

- (1) Lab coats must be worn at all times for work in the laboratory.
 - Consider a barrier-type lab coat in wet or damp environments
 - Turn in dirty or contaminated lab coats to stockroom for cleaning
- (2) Wear appropriate gloves for all procedures that may involve direct or accidental contact with blood, body fluids and other potentially infectious materials or infected animals. After use, remove gloves aseptically and wash hands afterward.
- (3) Safety glasses or splash goggles is standard PPE for BSL-2 work. Wear UV protective eyewear when there is potential exposure to UV sources.
- (4) A face shield over safety glasses/goggles must be worn when necessary to protect the face from splashes or impacting objects.
- (5) No open-toe footwear may be worn in BSL-2 laboratories.
- (6) No wearing of protective laboratory clothing outside the laboratory, e.g. in break rooms, offices, libraries, staff rooms and toilets.
- (7) Do not store protective laboratory clothing that has been used in BSL-2 work in the same lockers or cupboards as street clothing



3.0 Signs and Labels

- (1) Entry ways must be posted with a biohazard symbol, type of organism(s) and access requirements.
- (2) Refrigerators and freezers used with potentially infectious materials, and containers of biohazardous waste shall have labels with the word "BIOHAZARD" and the universal biohazard symbol in orange-red or red with lettering and symbols in a contrasting color. Waste containers may say "Biohazardous Waste" instead of "Biohazard".

4.0 Laboratory Space

- (1) Ample space must be provided for the safe conduct of laboratory work and for cleaning and maintenance.
- (2) Bench tops, walls, and floors should be smooth, easy to clean, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be slip-resistant.
- (3) Open spaces between and under benches, cabinets and equipment should be accessible for cleaning.
- (4) BSL-2 organisms and other potentially infectious materials must be in a locked space or otherwise secured from unauthorized access.
- (5) Hand washing facilities must be available in BSL-2 work spaces, preferably near the exit door.

5.0 Contamination and Exposure Prevention

- (1) Wash hands frequently and before leaving the laboratory.
- (2) Replace gloves as soon as practical when contaminated, torn, punctured, or when their ability to function as a barrier is compromised.
- (3) Materials must not be placed in the mouth do not lick labels or pens. Use only mechanical pipetting devices.
- (4) Food and drink shall not be stored in laboratory refrigerators, freezers, shelves, cabinets, or bench tops in BSL-2 labs.
- (5) Eating, drinking, smoking, applying cosmetics and handling contact lenses is prohibited in BSL-2 working areas
- (6) Storing human foods or drinks anywhere in BSL-2 working areas, including laboratory refrigerators, freezers, cabinets, etc. is prohibited. Closed water bottles kept in drawers or backpacks may be okay.
- (7) Perform technical procedures in a way that minimizes the formation of aerosols and droplets.
- (8) Perform procedures that may generate infectious aerosols in a biosafety cabinet, Class II or Class III. (At SF State, most of the biosafety cabinets are Class II.)

- (9) Disinfect the work area and lab equipment daily and after use
- (10) Transport biological agents between laboratories and campus buildings using rigid, leak-proof, double container systems lined with enough absorbent material to absorb liquid leaks.
- (11) Written Standard (Safe) Operating Procedures must be established for equipment and processes used to analyze living cells or microorganisms
- (12) Additional safety practices may be specified by your Principal Investigator or in the Biohazard Use Authorization.
- (13) Store, label, and handle biohazardous waste as described in **SECTION E**, parts 3-14.

6.0 Decontamination Basics

Decontaminate surfaces after work has ended. Selecting a disinfectant is based on several factors:

- What is the target organism(s) you want to inactivate?
- What are the physical characteristics of the surface to be disinfected?
 - Some disinfectants may corrode metal surfaces
- How long will the contact time be?
 - High concentrations of biological organisms may require longer contact

Common disinfectant types approved by the US EPA include the following:

- ◀ 0.5% sodium hypochlorite solution
- 70% Ethanol
- Quaternary Ammonium Compounds
- Phenolics

After blotting and wiping down a non-porous surface, allow the disinfectant to sit for the recommended minimum time. Examples: 10% bleach – 30 minutes; 70% ethanol – 10 minutes. Rinse the area with distilled water to remove residue.

To disinfect clothing or other porous materials, use 10% bleach and allow to soak for at least 30 minutes. Severely contaminated lab coats should be disposed of as biohazardous waste.

Disinfection with bleach

- 1. Only use household bleach containing 5% 9% sodium hypochlorite to make your 10% solution. Check the bleach bottle label to make sure. Laundry bleach, splashless bleach and some cheap brands may not be appropriate for disinfection.
- 2. Always make fresh bleach solution. Old bleach solutions lose effectiveness within 24 hours.
- 3. To make a 10% solution, you can use 1/3 cup of bleach per gallon of water, 4 teaspoons per quart (32 oz) of water, or 2 teaspoons in a 16 oz spray bottle filled with water.



7.0 Sharps and Universal Precautions

- (1) Do not bend, break, shear or remove needles from disposable syringes.
- (2) Limit the use of hypodermic needles and syringes. Do not use as substitutes for pipetting devices or for any purpose other than parenteral injection or aspiration of fluids from laboratory animals.
- (3) Dispose of contaminated sharps in a single-use, disposable container that is rigid, leak proof, puncture resistant, and labeled with the biohazard symbol and words, "SHARPS WASTE".
- (4) Place sharps waste containers near the point of use for immediate disposal and do not exceed the sharps container fill line or ³/₄ full.
- (5) Employ Universal Precautions when handling human and nonhuman primate tissues.
 - Handle all blood or bodily fluids as though they are potentially infectious for bloodborne pathogens
 - Consistently employ barrier protection with PPE (gloves, mucous membrane protection, lab coat)
 - Hepatitis B vaccination or declination form on file

8.0 Biohazardous Materials Spills

- (1) Do not attempt to clean up human vomit, feces, urine, or blood that is not directly involved in the research, academic project or exercise.
 - Isolate the affected area and contact stockroom staff or Facilities at 415.338.1538. After hours, contact UPD at 415.338.2222.
 - Custodians are trained to clean up human blood and body fluids in public areas and restrooms.
- (2) For small spills in laboratories, use Universal Precautions. Put on gloves and protective eyewear.
- (3) Prevent the spread of the spilled material by placing paper towels at the edges and then work inward to absorb more of the spillage.
- (4) Collect the absorbent in a plastic bag. Place contaminated gloves in the bag as well and close it. Place it into a red biohazard bag and attach a completed blue biowaste ID tag.
- (5) Use tongs to pick up paper towels soaked in a biohazardous liquid. If tongs are not available, double-glove.
- (6) Wipe down the affected area(s) with a mild detergent solution. Follow-up with a 10% bleach solution and let it sit for at least 30 minutes.
- (7) Report spills, accidents and overt or potential exposures to infectious materials to the laboratory supervisor.
- (8) The laboratory supervisor (or PI/instructor) must maintain a written record of such incidents and submit a copy to <u>Campus EH&S</u> via email or in person.



E. 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 (MWMA. The MWMA defines *biohazardous* waste is a subset of *medical* waste. (*California H&S Code Div. 20, Chapter 6.1, Sections 117600 – 118360)

Laboratory waste covered by this biosafety program manual is categorized as follows:

- Solid or dry, liquid or wet, pathology, or sharps waste.
- ◀ The nature of lab waste is that it can be either hazardous (BSL-2) or non-hazardous (BSL-1).

This section describes how these wastes are accumulated in the research and teaching laboratory and then treated to render it non-hazardous and/or non-recognizable.

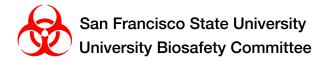
1.0 Basic Requirements

SFSU requires faculty, staff, and students to collect, treat, and dispose of biological waste responsibly in accordance with this program. The basic requirements for collecting and storing that apply to **all** biological waste are listed below:

- Container is in good condition.
- A blue BIO-WASTE tag or label is attached to container.
- Container is not over-filled. No spill-over is evident.
- Waste is not left in hallways or other non-lab-related areas

2.0 General Program Rules

- (1) Do not place items in biological waste bags that are likely to puncture the bag.
 - Plastic pipets and other disposable labware can puncture waste bags.
 - To avoid puncturing bags, place long pipets in the bag neatly laying them all in the same direction, double or triple bags used, or use a large sharps container.
- (2) Do not store waste in hallways or outside the generating lab.
- (3) Non-hazardous lab waste may not accumulate in the waste container for more than 30 days.
- (4) Biologically hazardous lab waste may accumulate a maximum of 7 days at room temperature.
- (5) If odor from waste poses a nuisance, remove waste for treatment or disposal within one (1) working day.
- (6) Do not place lab ware or objects that are obviously labware in standard trash cans. Labware must be disposed as lab waste even if it is unused or non-hazardous.



3.0 Labeling Biological waste

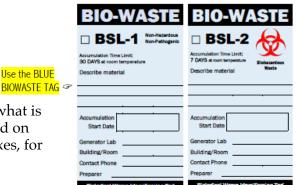
- (1) All biological waste containers must be labeled as follows:
 - Generator name and originating lab
 - Room number and contact number
 - Waste description
 - Accumulation start date
- (2) The blue **BIO-WASTE** tag provides information on the generator of the waste and what is inside the container. A completed tag is required on every bio-waste container, including sharps boxes, for the entire time waste is being accumulated.
- (3) For bags being autoclaved, remove the blue tag before placing in autoclave. Write the required information on the bag as listed in Section 9, "Requirements for Autoclaving Waste".
- (4) BSL-2 outer collection containers must be labeled with the biohazard symbol and the words "Biohazard" or "Biohazardous Waste" and be hard-sided, as described in Section 6, "Medical and Biohazardous Waste Storage (BSL-2)"

4.0 Biological Waste Categories

Laboratory waste is handled as either non-hazardous (BSL-1) or hazardous (BSL-2). See *Biological Waste Flow Chart* in Appendix B for details. There are four general categories of biological waste streams:

Solid/Dry Pathology Liquid/Wet Sharps

- (1) The Solid or Dry Waste category includes the following materials
 - Cell cultures and bacterial waste, cells, gels, petri dishes, eggs, freeze-dried bacterial or fungi, cultures.
 - Contaminated debris or supplies i.e., Gloves, paper towels, pipette tips, liners
- (2) The Liquid or Wet Waste category includes the following materials
 - Liquid cell cultures
 - Liquid bacterial wastes
- (3) The Pathology Waste category includes the following materials
 - Liquid human or animal blood
 - Human remains
 - Animal remains
- (4) The Sharps Waste category includes the following materials
 - Syringes with needles
 - Scalpels and razor blades
 - Glass slides and pipets





5.0 Non-Hazardous Biological Waste (BSL-1)

- (1) Non-pathogenic, "non-biohazardous", waste must be stored in containers labeled as "BSL-1 waste" or as "non-biohazardous".
 - Waste to be autoclaved shall be stored in CLEAR autoclavable bags inserted in a rigid outer container.
 - Obtain CLEAR autoclave bags or sturdy CLEAR waste bags (not for autoclaving) from stockroom staff.
 - If present, cover up or remove the "BIOHAZARD" symbol or word on containers that don't have biohazardous/medical waste in them.
 - Waste collection containers must be a color other than red or orange for BSL-1 waste, if it is not pathogenic or a biohazard.
 - Objects that are obviously "lab waste"—even if not hazardous or contaminated—must be placed in a box or bagged to avoid the question of whether this is supposed to be in the trash or not.

NOTE: CLEAR non-autoclavable waste bags are the same bags used to collect chemical dry waste.

- (2) The blue bio-waste identification tags are intended to clearly communicate the information in (1) above to visitors, EHS staff, and inspectors.
 - Attach tags to containers storing biological waste.
 - Autoclavable bags—Recommend that you attach the tag to the outer container not to the bag itself.
 - You must write generator name, etc. onto individual autoclave bags and disposable waste containers that will be autoclaved. (See requirements in item #8 of this section.)
 - Remove the tag from containers before placing into autoclave
- (3) Accumulate biological lab waste in a designated location where it will not be mixed with standard trash. When ready for disposal or treatment, secure bag or container and remove. Do not store waste in hallways or outside the generating lab.
 - BSL-1 lab waste may not accumulate in the container for more than 30 days at room temperature. Dispose or treat promptly.
 - If odor from waste poses a nuisance, the waste must be removed for treatment or disposal within 1 working day
- 4) Liquids, such as liquid cell cultures, must be disinfected before drain disposal. This is to prevent issues arising in the sewage treatment plant downstream.
- 5) BSL-1 non-hazardous waste stored in red bags must meet all of the container, signage and storage requirements of BSL-2 waste.

6.0 Medical and Biohazardous Waste Storage (BSL-2)

(1) Biohazardous waste or medical waste includes BSL-2 materials, human blood or blood components, pathology wastes such as human or animal tissues, and red sharps containers and bags.



- (2) Articles that are contaminated with blood components, but not don't have fluid blood in them, may be autoclaved.
- (3) Storage container requirements:
 - Bag must be RED.
 - Outer container may be red or any other color.
 - Bag must be placed in a rigid, leak-resistant container, with a tight-fitting lid
 - Container must be kept closed when not adding waste
 - "BIOHAZARD" symbol and "BIOHAZARD" word must be on the lid and sides of container. The word "BIOHAZARDOUS WASTE" may be substituted if preferred.
 - Pathology waste collection containers must also be labeled "PATHOLOGY WASTE".
- 4) Biohazardous and medical wastes may be stored only for a limited time:
 - The window for accumulating and storing biohazardous waste in the generating lab—at room temperature— is 7 DAYS —regardless of whether the container is full.
 - The countdown begins on the accumulation start date recorded on the blue tag. In a freezer (below 32°F), waste may be stored up to 90 days.
- 5) Biohazardous waste collection rooms must be kept locked and a sign meeting the requirements of the California Medical Waste Management Act (MWMA) must be posted on the door. Waste must be picked up at least weekly by a qualified contractor for appropriate disposal.

6.1 Red Biohazard Bag Criteria

All red biohazard bags used at SFSU must meet California Medical Waste Management Act (MWMA) criteria as stated in MWMA, Chapter 2, 117630, Definition of "Biohazard Bag".

If you are not sure of your existing bags, contact the vendor for the information.

- Biohazard bags intended for DOT-approved shipping containers to transport waste from the generating facility to the treatment and disposal facility must be certified and marked as having passed the tests prescribed for tear resistance in ASTM D1922 and impact resistance in ASTM*D1709.
- Biohazard bags used to collect medical waste in the facility only need to pass the ASTM D1709 dart drop test IF AND ONLY IF these are either not used to transport waste off-site OR the bags are placed in a DOT shipping container lined with certified bags as described above for off-site shipping.
 - Waste that has been autoclaved and is not intended for off-site transportation may fall under this category show that it meets the ASTM D1709 dart drop test.
 - Per SFSU protocol, after autoclaving, such red autoclave bags are over-packed into heavy-duty opaque trash bags before disposal into municipal trash.
 - Autoclaved waste is sterilized therefore it is no longer "biohazardous".

To avoid confusion and potential non-compliance, as of August 1 2018, all new red biohazard bags purchased must be both ASTM D1709 and ASTM D1922 certified.

* *ASTM* = *American Society for Testing Materials*

**DOT = United States Department of Transportation



7.0 Pathology Waste

This type of waste is defined as any human or animal body parts, such as organs, tissues, surgical specimens, and includes blood and other body fluids from research, experiments, and surgery.

7.1 Pathology Waste: Animal Tissues and Remains (Academic Labs)

At SFSU, academic laboratory courses use deceased laboratory animals from vendors that routinely supply educational institutions and are vetted as non-infectious. During storage and use, these materials are considered BSL-1, non-hazardous. Once remains become waste, they are then packaged as "pathology waste" in red biohazard bags as a courtesy to the waste contractor.

When ready for disposal, contact the Animal Facilities Manager at x8-6336 to arrange for storage in the freezer.

7.1.1 Liquid Sheep or Other Animal Blood

There are two options for non-infectious animal blood from sheep or other animals.

- Package as biohazardous "pathology" waste, even if sterile, with a BLUE bio-waste tag attached to the red back covering container.
- Disinfect with 0.5% sodium hypochlorite solution then dispose of into sink drain

7.2 Pathology Waste: Live Animal Remains (Research)

Animal care and waste disposal is governed by the IACUC. Below is a brief overview of the protocol for disposing of animal waste. SFSU treats disposal of animal remains from research activities as pathology waste whether infectious or not.

- (1) Notify the Animal Facilities at x8-6336 when animal carcasses and associated animal wastes are ready for disposal. The Campus uses a licensed biohazardous waste contractor 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 1.9 milspec thick. If contaminated with blood or other fluids, treat as biohazardous waste and place in red biohazard bag.
- (3) Lab personnel must notify Animal Facilities to make an appointment before take animal remains to the storage freezer in HH 815. Remains must be wrapped in red biohazard bags when in the freezer.
- (4) Fill out the freezer log with the information below:
 - Date
 - Name of principal investigator or class instructor
 - 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 Facilities Manager and put a label on the bag. Include this 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) When ready for pick-up, refrigerated and frozen animal waste will be placed into a red biohazard bag lined storage drum as directed by the Animal Care Coordinator.
 - Drum cover must remain on when not adding waste
 - Drum must be labeled "PATHOLOGY WASTE" in addition to having the BIOHAZARD symbol and words.

7.3 Pathology Waste: Human Remains and Tissues

- (1) Anatomy lab cadavers and body parts are removed by a licensed contractor as directed by the Biology Stockroom and returned to UCSF.
- (2) Human tissues and blood (in liquid form) are medical waste and must be disposed of through a licensed contractor. Contact the Biology Stockroom for assistance in disposal of human blood and other body fluids.
- (3) This plan does not cover sewage handling or disposal.

8.0 Sharps Waste

Sharps include items such as scalpels, needles, and other objects that can easily cut or penetrate skin. For these types of items, "Sharps" Containers have been purchased to protect users and room occupants.

- (1) **Sharps containers** may accumulate waste until full. Attach a completed blue SHARPS biowaste tag. Containers MUST have the "BIOHAZARD" symbol and word.
- (2) Fill sharps container to either the marked fill line or ³/₄ full
- (3) Do not overfill the container.
- (4) Do not remove items from the container, especially by hand.
- (5) When full, close container tightly or tape shut.
- (6) Do not store a full, closed sharps container longer than 30 days in the lab.
- (7) Collect laboratory sharps (i.e., needles, scalpels) in an approved sharps container whether biohazardous or not.
 - Clean broken glassware may be placed in a cardboard or plastic box and taped shut. Write "broken glass" on the box. May be disposed of in standard municipal trash bins.
- 8) Objects capable of puncturing an autoclave bag should be placed in a bucket or other hard-sided container that can be autoclaved.
 - Plastic serological pipets, etc. will melt at autoclave temperatures, removing the capability of punctures.
 - After autoclaving, glass objects that are extra-long may be placed in a hard-sided box or container, taped up, marked "Glass" or "Broken Glass", and then placed in standard trash receptacles.



9.0 Chemical Disinfection

Biohazardous waste may be treated by chemical disinfection if it is liquid or semi-liquid and the chemical disinfection method is recognized by the NATIONAL INSTITUTES OF HEALTH, the CENTERS FOR DISEASE CONTROL AND PREVENTION, or the AMERICAN BIOLOGICAL SAFETY ASSOCIATION.

Following treatment by chemical disinfection, the medical or biohazardous waste may be discharged to the public sewage system if the discharge is consistent with waste discharge requirements in the Campus discharge permit.

Waste from liquid cell cultures may be bleached with a 0.5% sodium hypochlorite solution for at least 30 minutes before disposal.

- Know how to tell if the organisms have all been killed.
- If necessary, add more bleach and allow to sit overnight.
- Do not autoclave bleached waste.

10.0 Sterilization at SFSU

The department of Biology is permitted to sterilize and dispose of waste using standard protocols.

SFSU policy is that most biological waste materials must be autoclaved or otherwise disinfected or sterilized before they may be disposed of—whether confirmed to be infectious or not.

Departments generating biological wastes are responsible for following the sterilization practices and disposal protocols in this Biosafety Program Manual.

These microbiological and biohazardous materials may be sterilized by autoclave before disposal.

- Human or animal culture specimens from pathology labs.
- Cultures and stocks of microorganisms from research and instructional labs.
- Waste from production of bacteria, viruses, or use of spores.
- Culture dishes and devices used to transfer, inoculate, and/or mix cultures.
- Waste containing any microbiological specimens or cultures

Important: Not all biological materials may be autoclaved at SFSU. Those that can't be treated on site will be disposed of off-site using a licensed contractor.

The University does NOT AUTOCLAVE the following biological wastes. These waste streams are disposed of through licensed contractors. Contact the Biology Stockroom for more information.

- Human waste from the anatomy lab
- Research animals and tissues
- Fluid human blood and other bodily fluids
- Sharps containers
- Organic solvents or other chemical hazardous waste



11.0 Autoclave Use Policy

- (1) Autoclave users must be trained before using these machines.For Biology autoclaves contact BIS Facility at x8-2288.
- (2) Procedures for using the autoclave must be posted or available at each location.

Autoclaves used to treat waste

Biology HH 405, HH 530, HH 617 (2) HH 632 (BIS Facility)

- (3) Users must record an entry in the logbook for each use
- (4) Keep doors locked and the autoclaves on access code screen.
- (5) User is responsible for cleaning up spills or melted plastic in the autoclave or room.
- (6) Faculty/Principal Investigators and Staff Managers are responsible for making sure their personnel using the autoclaves have received the mandatory training and follow the posted protocols.
- (7) Annual refresher training is required for users with BSL-2 waste.
- (8) Departments with autoclaves used to treat waste must designate someone to keep the following records for at least three years:
 - Records of autoclave training
 - Record of monthly biological indicator testing
 - Records of maintenance and servicing

12.0 Requirements for Autoclaving Waste

- (1) Biohazard bags and other biological waste containers must be of a type suitable for autoclaving at temperatures of at least 121° C.
- (2) Make sure the waste is suitable for autoclaving. Sharps, animal or human tissue, liquid blood, and chemicals may NOT be autoclaved.
- (3) 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;
 - Building and room number where the waste was generated;
 - Telephone extension
- (4) Autoclave (heat-sensitive) tape at least 6 inches long is required on all autoclave bags or containers—even if the bag comes with its own indicator—to ensure sterilization temperatures have been reached.
- (5) Use the correct cycle for your type of waste as indicated by the posted instructions or the responsible faculty or staff manager.
- (6) Confirm sterilization before disposal. To confirm sterilization, check to make sure the indicator tape (or indicator on bag) has changed from white to black and white stripes.
- (7) Allow to cool before placing in opaque disposal bag.



13.0 Problems with Autoclaves

If something breaks or spills or an autoclave breaks down, the user is responsible to act as follows:

- (1) Post a sign indicating machine is non-operational and/or the area is closed for clean-up. Include date and basic problem.
- (2) Notify BIS Facility staff (Biology autoclaves) as soon as possible and provide key information about the incident.
- (3) If you can safely do so, clean up spills, broken glassware, melted plastic, and clear out debris from the autoclave drain within the autoclave machine and/or the autoclave room.
- (5) Do not use any sharp objects within the autoclave.
- (6) Wait for BIS or Stockroom staff to notify you that the machine is once again operational.
- (7) Once the problem has been taken care of, remove any posted warning signs.



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APPENDIX A – Review and Update Log

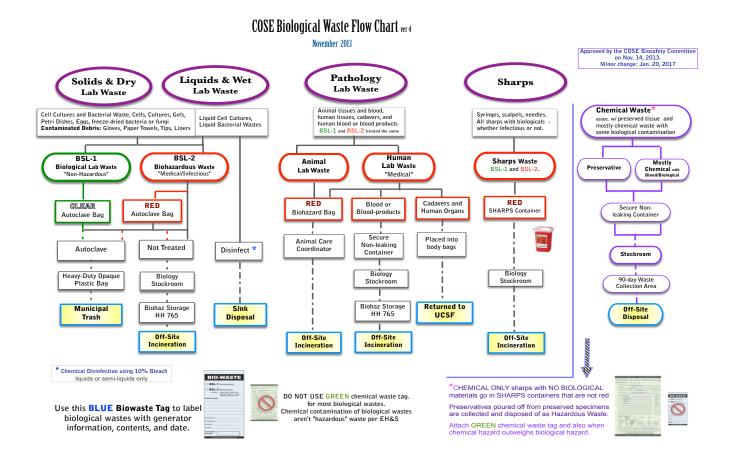
| Date | Notes or Details | Sections or Pages | Signature |
|----------------|--|---|--------------|
| April 22, 2022 | 2019 manual was a major update. 2022 - Changed immunocompromised text as that term is no longer used to identify a group in the 6 th ed of the BMBL | Part A, Section 10 Pages 4 and 5 | Linda Vadura |
| May 6, 2022 | Used the Accessibility Checker in MS Word to improve accessibility. | Whole Document | Linda Vadura |
| Jan 22, 2024 | Added a statement about pregnancy status and review of their situation and risks with their personal medical provider. Removed language about a training handout being available. | Part A, Section 10, Page 4 and 5 | Linda Vadura |
| Jan 22, 2024 | Aerosol Transmissible Diseases was edited for clarity. Changed ATD for Zoonoses to contact IACUC for information. Added BSL-2* to the biosafety level listing. Clarified language in subsection C about BSL-2* requirements. Changed 10% bleach solution to 0.5% sodium hypochlorite solution where necessary. Clarified what is meant by a 10% bleach solution and how household bleach with 5%-9% sodium hypochlorite is required. Added a short section on properly using bleach to disinfect. | Part A, Section 9, Page 4 Part B, Page 8 App. C, Page 30 Part E, Section 9, Chemical Disinfection, Page 23 Part D, Section 6, Decontamination Basics, Page 15 | Linda Vadura |
| | | | |



| Date | Notes or Details | Sections or Pages | Signature |
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APPENDIX B – Biological Waste Disposal Chart





APPENDIX C – Aerosol Transmissible Disease Program - Lab

Cal/OSHA's Aerosol Transmissible Diseases (ATD) Standard, in 8 CCR 5199, applies to laboratory operations when employees perform procedures capable of aerosolizing Airborne Transmissible Pathogens (ATPs-L).

- Organisms requiring BSL-3 controls
- Organisms specified in Appendix D of the ATD Standard.

At SFSU, laboratory operations are required to comply with subsections (a) and (f) of the ATD Standard, along with subsections (i) and (j) where Cal/OSHA's Respiratory Protection Standard (8 CCR 5199) is mentioned.

Laboratories in which employees have direct contact with cases or suspected cases of ATD or with potentially infected cadavers are required to comply with the full provisions of the ATD Standard.

Assessing Risk and Controls

The ATD requires that the institution's Biological Safety Officer performs risk assessments in accordance with methodology included in Section II of the BMBL for each agent covered by the Standard. For the purposes of ATD compliance, the campus biosafety programs coordinator serves as the Biological Safety Officer (BSO).

At SFSU, all uses of biohazardous materials must go through a biohazard use authorization process. The risk assessment is done by members of the University Biosafety Committee (BSC) in addition to the BSO.

At SFSU, use of biohazardous materials is limited to those requiring BSL-2 controls. BSL-3 and above are prohibited University owned or controlled properties or facilities. Because of this prohibition, Cal/OSHA's ATD Standard only covers those listed in Appendix D of that standard.

ATD Exposure Control/Biosafety Plan

The SFSU Biosafety Program Manual (aka Biosafety Plan in the ATD Standard) incorporates practices and procedures to minimize employee exposure to all biohazardous aerosols generated in laboratory operations, not just Aerosol Transmissible Pathogens (ATP-L).

- A. The person serving as the Biosafety Officer responsible for implementing the Biosafety Program is Linda Vadura, EH&S, at 415.338.2565
- B. Job classifications in which all or some employees have occupational exposure:

| Faculty researcher | Laboratory staff |
|--------------------|---------------------------------------|
| Faculty instructor | Official Volunteer Employees |
| Student Employees | Technical Support or Operations Staff |





Tasks and procedures in which employees have occupational exposure

- Preparing cultures and other materials for classroom use
- Handling and manipulating cells, bacteria, and culture for research use
- Pipetting, centrifuging, and sonicating biological materials for research use
- Handling and treating biohazardous waste
- Decontaminating and disinfecting surfaces and in contact with biohazardous material
- C. ATPs-L known or reasonably expected to be present in laboratory materials (from Appendix D): *Salmonella* spp

Biosafety measures include using techniques to minimize the generation of aerosols and using a biosafety cabinet when using BSL-2 materials and BSL-2* materials (BSL-2 controls plus requirements of this ATD plan).

- D. All materials containing ATPs-L will be treated as infectious material until verified that the pathogen has been deactivated or attenuated.
- E. Biosafety cabinets will be sued to contain potentially infectious laboratory aerosols. When a biosafety cabinet cannot be used, centrifuges and other large equipment will be sealed or equipped with controls to prevent aerosols from escaping.
- F. Safe handling procedures have been established to minimize employee exposure to infectious agents. Sniffing in vitro cultures and other known unsafe practices are prohibited. Employees who work with biohazardous materials are required to complete an online course, "Working Safely with Biohazards" that reviews safe handling procedures.
- G. Effective decontamination and disinfection procedures are described in the Biosafety Program Manual and online training course, and further discussed by staff and faculty supervisors with their workers.
- H. Disposable gloves and lab coats are the minimum personal protective equipment required to work with biohazardous materials. Eye protection is required whenever a splash or aerosol hazard exists.
- I. Regular tasks and operations do not require respiratory protection. A NIOSH approved N95 respirator is an option when engineering controls, such as use of a biosafety cabinet, is not feasible. Use of respirators for non-routine tasks or operations that require respiratory protection as determined by the Biological Safety Officer, will comply with the campus respirator program and 8 CCR 5199, Cal/OSHA Respiratory Protection Standard. If a more protective respirator is indicated, the work may not be done at SFSU.
- J. SFSU does not use BSL-3 materials. The *Salmonella* spp in use in SFSU laboratories will not result in uncontrolled releases of ATP-L requiring reporting to the local health officer.
- K. Medical services will be provided as needed for employees using organisms covered by the ATD Standard through a contracted licensed occupational medical services provider. All tests will be performed by an accredited laboratory.

Biohazardous materials or pathogens that may require employee medical surveillance or immunizations will be identified as part of the Biohazard Use Authorization process (as described in the Biosafety Program Manual).



There are no immunizations currently available for Salmonella spp. and no applicable public health guidelines for laboratory use.

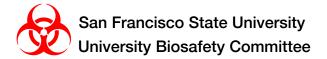
Research and teaching activities at SFSU do not involve the use of materials containing M. Tuberculosis so surveillance for latent TB (LTB1) is not necessary or provided.

Appendix D of §5199: Aerosol Transmissible Pathogens – Laboratory (Mandatory)

Appendix D of the ATD Standard contains a list of agents that, when reasonably anticipated to be present, require a laboratory to comply with Section 5199 for laboratory operations by performing a risk assessment and establishing a biosafety plan that includes appropriate control measures as identified in the standard. Below is an excerpt from Appendix D. <u>ATD Standard Appendix D</u>

Adenovirus (in clinical specimens and in cultures or other materials derived from clinical specimens)

- Arboviruses, unless identified individually elsewhere in this list (large quantities or high concentrations* of arboviruses for which CDC recommends BSL-2, e.g., dengue virus; potentially infectious clinical materials, infected tissue cultures, animals, or arthropods involving arboviruses for which CDC recommends BSL-3 or higher, e.g., Japanese encephalitis, West Nile virus, Yellow Fever)
- Arenaviruses (large quantities or high concentrations of arenaviruses for which CDC recommends BSL-2, e.g., Pichinde virus; potentially infectious clinical materials, infected tissue cultures, animals, or arthropods involving arenaviruses for which CDC recommends BSL-3 or higher, e.g., Flexal virus)
- *Bacillus anthracis* (activities with high potential for aerosol production**, large quantities or high concentrations, screening environmental samples from *b. anthracis* -contaminated locations)
- *Blastomyces dermatitidis* (sporulating mold-form cultures, processing environmental materials known or likely to contain infectious conidia)
- *Bordetella pertussis* (aerosol generation, or large quantities or high concentrations)
- *Brucella abortus, B. canis, B. "maris", B. melitensis, B. suis* (cultures, experimental animal studies, products of conception containing or believed to contain pathogenic *Brucella* spp.)
- *Burkholderia mallei, B. pseudomallei* (potential for aerosol or droplet exposure, handling infected animals, large quantities or high concentrations)
- Cercopithecine herpesvirus (see Herpesvirus simiae)
- *Chlamydia pneumoniae* (activities with high potential for droplet or aerosol production, large quantities or high concentrations)
- *Chlamydia psittaci* (activities with high potential for droplet or aerosol production, large quantities or high concentrations, non-avian strains, infected caged birds, necropsy of infected birds and diagnostic examination of tissues or cultures known to contain or be potentially infected with *C. psittaci* strains of avian origin)
- *Chlamydia trachomatis* (activities with high potential for droplet or aerosol production, large quantities or high concentrations, cultures of lymphogranuloma venereum (LGV) serovars, specimens known or likely to contain *C. trachomatis*)



- *Clostridium botulinum* (activities with high potential for aerosol or droplet production, large quantities or high concentrations)
- *Coccidioides immitis, C. posadasii* (sporulating cultures, processing environmental materials known or likely to contain infectious arthroconidia, experimental animal studies involving exposure by the intranasal or pulmonary route)

Corynebacterium diphtheriae

Coxiella burnetti (inoculation, incubation, and harvesting of embryonated eggs or cell cultures; experimental animal studies, animal studies with infected arthropods, necropsy of infected animals, handling infected tissues)

Crimean-Congo haemorrhagic fever virus

Cytomegalovirus, human (viral production, purification, or concentration)

Eastern equine encephalomyelitis virus (EEEV) (clinical materials, infectious cultures, infected animals or arthropods)

Ebola virus

Epstein-Barr virus (viral production, purification, or concentration)

Escherichia coli, shiga toxin-producing only (aerosol generation or high splash potential)

Flexal virus

Francisella tularensis (suspect cultures—including preparatory work for automated identification systems, experimental animal studies, necropsy of infected animals, high concentrations of reduced-virulence strains)

Guanarito virus

Haemophilus influenzae, type b

- Hantaviruses (serum or tissue from potentially infected rodents, potentially infected tissues, large quantities or high concentrations, cell cultures, experimental rodent studies)
- Helicobacter pylori (homogenizing or vortexing gastric specimens)
- Hemorrhagic fever -- specimens from cases thought to be due to dengue or yellow fever viruses or which originate from areas in which communicable hemorrhagic fever are reasonably anticipated to be present

Hendra virus

Hepatitis B, C, and D viruses (activities with high potential for droplet or aerosol generation, large quantities or high concentrations of infectious materials)

Herpes simplex virus 1 and 2

- Herpesvirus simiae (B-virus) (consider for any material suspected to contain virus, mandatory for any material known to contain virus, propagation for diagnosis, cultures)
- *Histoplasma capsulatum* (sporulating mold-form cultures, propagating environmental materials known or likely to contain infectious conidia)

Human herpesviruses 6A, 6B, 7, and 8 (viral production, purification, or concentration)

Influenza virus, non-contemporary human (H2N2) strains, 1918 influenza strain, highly pathogenic avian influenza (HPAI) (large animals infected with 1918 strain and animals infected with HPAI strains in ABSL-3 facilities, loose-housed animals infected with HPAI strains in BSL-3-Ag facilities)



Influenza virus, H5N1 - human, avian

Junin virus

Kyasanur forest disease virus

Lassa fever virus

- *Legionella pneumophila,* other legionella-like agents (aerosol generation, large quantities or high concentrations)
- Lymphocytic choriomeningitis virus (LCMV) (field isolates and clinical materials from human cases, activities with high potential for aerosol generation, large quantities or high concentrations, strains lethal to nonhuman primates, infected transplantable tumors, infected hamsters)

Machupo virus

Marburg virus

Measles virus

Monkeypox virus (experimentally or naturally infected animals)

Mumps virus

Mycobacterium tuberculosis complex (M. africanum, M. bovis, M. caprae, M. microti, M. pinnipedii, M. tuberculosis (aerosol-generating activities with clinical specimens, cultures, experimental animal studies with infected nonhuman primates)

Mycobacteria spp. other than those in the M. tuberculosis complex and M. leprae (aerosol generation)

Mycoplasma pneumoniae

- *Neisseria gonorrhoeae* (large quantities or high concentrations, consider for aerosol or droplet generation)
- *Neisseria meningitidis* (activities with high potential for droplet or aerosol production, large quantities or high concentrations)

Nipah virus

Omsk hemorrhagic fever virus

Parvovirus B19

Prions (bovine spongiform encephalopathy prions, only when supported by a risk assessment)

- Rabies virus, and related lyssaviruses (activities with high potential for droplet or aerosol production, large quantities or high concentrations)
- Retroviruses, including Human and Simian Immunodeficiency viruses (HIV and SIV) (activities with high potential for aerosol or droplet production, large quantities or high concentrations)
- *Rickettsia prowazekii, Orientia (Rickettsia) tsutsuagmushi, R. typhi (R. mooseri),* Spotted Fever Group agents (*R. akari, R. australis, R. conorii, R. japonicum, R. rickettsii, and R. siberica*) (known or potentially infectious materials; inoculation, incubation, and harvesting of embryonated eggs or cell cultures; experimental animal studies with infected arthropods)

Rift valley fever virus (RVFV)

Rubella virus

Sabia virus

Salmonella spp. other than S. typhi (aerosol generation or high splash potential)

Salmonella typhi (activities with significant potential for aerosol generation, large quantities)



SARS coronavirus (untreated specimens, cell cultures, experimental animal studies)

Shigella spp. (aerosol generation or high splash potential)

Streptococcus spp., group A

Tick-borne encephalitis viruses (Central European tick-borne encephalitis, Far Eastern tick-borne encephalitis, Russian spring and summer encephalitis)

Vaccinia virus

Varicella zoster virus

Variola major virus (Smallpox virus)

Variola minor virus (Alastrim)

Venezuelan equine encephalitis virus (VEEV) (clinical materials, infectious cultures, infected animals or arthropods)

West Nile virus (WNV) (dissection of field-collected dead birds, cultures, experimental animal and vector studies)

Western equine encephalitis virus (WEEV) (clinical materials, infectious cultures, infected animals or arthropods)

Yersinia pestis (antibiotic resistant strains, activities with high potential for droplet or aerosol production, large quantities or high concentrations, infected arthropods, potentially infected animals)

* 'Large quantities or high concentrations' refers to volumes or concentrations considerably in excess of those typically used for identification and typing activities. A risk assessment must be performed to determine if the quantity or concentration to be used carries an increased risk, and would therefore require aerosol control.

** 'activities with high potential for aerosol generation' include centrifugation