

Biosafety Manual

Responsible Administrator: Biosafety Officer

Revised: January 2024

Summary: This section outlines the policy and procedures related to the Biosafety Manual that is administered through the Environmental Health and Safety (EHS) Department.

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1.0 PURPOSE

The purpose of the UC Irvine Biosafety Manual is to specify the practices, procedures and requirements for the safe handling and use of biohazardous materials for research, clinical and teaching activities at UCI and UCI Medical Center research facilities.

2.0 SCOPE

The UCI Biosafety Manual applies to all UCI faculty, staff, hosted visitors, students, participating guests and volunteers, contract laborers, supplemental personnel and employees of firms working at locations where UCI has management control of specific biohazards, including:

- All infectious agents (bacteria, fungi, parasites, prions, rickettsia, viruses, etc.) which can cause disease in humans or cause significant environmental or agricultural impact.
- Human, primate cells or cell culture
- Recombinant and Synthetic Nucleic Acids
- Transgenic plants, insects, or animals
- Human gene therapy research
- Animals and animal products known to be reservoirs of zoonotic diseases

UCI supports research utilizing BSL-1, BSL-2, and BSL-3 containment and work practices. There are no BSL-4 laboratories at UCI.

The following locations are not covered by this Biosafety Manual:

- UCI Medical Center School of Medicine clinical locations; and
- UCI Medical Center hospitals and clinics directly covered under the hospitals' license.

3.0 POLICY

UCI is committed to maintaining a safe working environment in research and teaching laboratories where biological materials are used. As the foundation of that commitment, UCI and its policies comply with all federal and state regulations and guidelines governing the use of biological materials.

- Federal
 - Biosafety in Microbiological and Biomedical Laboratories ([BMBL](#)), Centers for Disease and Control (CDC)
 - Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), National Institutes of Health (NIH)
 - National Select Agent Registry, CDC
 - Primary Containment for Biohazards: Selection, Installation and Use of Biological Safety Cabinets, CDC
 - Shipping Domestic
 - Additional Requirements of Facilities Transferring and Receiving Select Agents, CDC
 - Import and Export, Animal and Plant Health Inspection Service, USDA
 - Select Agents and Toxins, Code of Federal Regulations Title 42: Public Health, Part 73
 - Research and Special Programs Administration, Department of Transportation (DOT)
 - Shipping Infectious Substances, Code of Federal Regulations Title 49, Parts 100-185, DOT
 - Shipping – International
 - Guidelines for the Safe Transport of Infectious Substances and Diagnostic Specimens, World Health Organization (WHO)
 - Transportation of Dangerous Goods by Air, International Air Transportation Association (IATA)

- State
 - Aerosol Transmissible Diseases, California Code of Regulations, Title 8, Section 5199
 - California Bloodborne Pathogens Standard, State of California, Division of Occupational Safety and Health (DOSH) 8 CCR §5193
 - Medical Waste Management Act, California Health and Safety Code (HSC), Section 117600-118360
- UC Irvine
 - Institutional Biosafety Committee (IBC) Program

4.0 RESPONSIBILITIES

4.1 VICE CHANCELLOR FOR RESEARCH

The Vice Chancellor shall provide resources and support to:

- Establish policies that provide for safe conduct of research and teaching involving biohazardous materials.
- Maintain an active Institutional Biosafety Committee.
- Ensure compliance with the regulations and guidelines by Principal Investigators conducting research at UCI.

4.2 INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

The [UCI Institutional Biosafety Committee](#) (IBC) was created under mandate from the National Institutes of Health (NIH). The IBC is a faculty-led committee appointed by the UCI Vice Chancellor for Research (VCR). The IBC is responsible for establishing, monitoring, and enforcing policies and procedures involving hazardous biological materials and recombinant/synthetic nucleic acids to meet applicable federal, state, local, and institutional regulations, and guidelines. The IBC reviews and approves biological use authorizations (BUAs) for academic research and teaching laboratories involving biohazardous materials.

4.3 PRINCIPAL INVESTIGATOR

The Principal Investigator (PI) is defined as the faculty member in whose assigned space a research activity is conducted. For more information about PI status, visit the Office of Research webpage on [Lead Researcher Eligibility](#).

Responsibilities of the PI include:

- Ensure the health and safety of all individuals who enter or work in their laboratory.
- Ensure compliance with applicable regulations and criteria established in this Biosafety Manual.
- Notify the IBC prior to the initiation of work required the use of biohazardous materials.
- Ensure that any research projects requiring approval prior to the initiation of work by the NIH Guidelines, or any other agency be reviewed and approved by the IBC prior to obtaining agency approval.
- Ensure that specific laboratory hazards are effectively communicated to all individuals who enter and/or work in advance.
- Ensure that personnel have received appropriate training and are competent to perform procedures used in the laboratory.
- Develop laboratory-specific standard operating procedures (SOPs) that cover the hazards and activities relevant to the laboratory.
- Ensure that engineering controls are available, in good working order, and are used appropriately to minimize exposure to biohazardous materials.
- Ensure that appropriate personal protective equipment is available and used by laboratory personnel.
- Ensure that laboratory workers are provided immunizations and medical surveillance prior to, and in the event of, exposure to biohazardous materials as appropriate (based on CDC and the IBC).
- Report any significant problems, violations of the policies, practices and procedures set forth in this Biosafety Manual, or any significant research related accidents and illnesses to the Biosafety Officer within 24 hours at (949 824-6200) and ibc@uci.edu.

- Develop (with the assistance of the Biosafety Officer) emergency plans for handling accidental spills and personnel contamination.
- Comply with shipping requirements for biohazardous materials and infectious agents.
- Ensure that biological material is disposed of according to regulations, as outlined in this Biosafety Manual.
- Ensure that periodic inspections of the laboratory conducted with EHS and a laboratory representative.

4.4 UCI BIOSAFETY OFFICER

The UCI Biosafety Officer (BSO) is appointed by the University and is a staff member of Environmental Health and Safety and serves as a member of the IBC. The Biosafety Officer's duties include, but are not limited to:

- Conduct periodic inspections to ensure that required laboratory practices and procedures are rigorously followed.
- Assist PIs and research staff in developing exposure control plans and provide technical advice to facilitate safe handling, storage, and use of biohazardous materials.
- In consultation with faculty, staff, and the IBC; develop and implement policies, procedures, and practices to reduce the risks of work with biohazardous materials with consideration given to minimizing interference with the conduct of research and teaching.
- Develop emergency plans for handling accidental spills and personnel contamination. Investigate laboratory accidents involving biohazardous materials research.
- Review proposed biohazardous materials work. Act within guidelines established by the IBC, approve low risk activities and forward all other proposals to the IBC.
- Plan, develop and conduct training on biosafety issues, practices, and procedures.
- Review and approve laboratory-specific training plans for high-hazard biohazardous materials research laboratories.
- Report to the IBC any significant problems, violations of UCI biosafety policies, practices or procedures and any significant research related accidents or illnesses of which the Biosafety Officer becomes aware.
- Implement the decisions of the IBC.
- Serve as a liaison between the PI's and the IBC.
- Serve as a liaison between the PI's and Regulatory Agencies.
- Review biosafety facility construction/remodeling plans and specifications. Inspect construction/remodeling and authorize initiation of biohazardous materials work following completion of construction.
- Provide advice on biosafety facility design, ventilation needs and other supporting services.
- Advise on the selection, installation, maintenance, and use of laboratory equipment which provides or aids in containment of biohazardous materials.

4.5 LABORATORY STAFF

Whoever works in the laboratory in a technical (rather than purely administrative) capacity is defined as a laboratory worker even if the person is a faculty member, student, intern, visiting scholar, or volunteer. It is required that laboratory staff be listed on the BUA. Their responsibilities include:

- Conscientiously follow lab-specific biosafety practices and procedures.
- Report to the PI or the lab supervisor all problems, violations in procedure or spills as soon as they occur.
- Report to the BSO any significant violations in biosafety policy, practices or procedures which are not resolved by the Principal Investigator within a reasonable amount of time.
- Refuse to take any adverse action against any person for reporting real or perceived problems or violations of procedures to supervisors, the PI, the BSO, or the IBC.

5.0 PROGRAM COMPONENTS

5.1 INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW AND BIOLOGICAL USE AUTHORIZATION (BUA) APPROVAL PROCESS

The IBC protocol review process is one in which comprehensive review is made of all work going on or proposed in any given laboratory. Approval given for such work applies for a three-year period, after which it becomes subject to review and renewal. All labs must complete the steps below if conducting projects involving the use of:

Material
Recombinant/synthetic nucleic acid molecules
Infectious agents that can cause disease in healthy humans and/or significant environmental or agricultural impacts
Select agents and select toxins
Human and nonhuman primate materials
Genetically modified animals and whole plants

BRIEF OVERVIEW

1. Projects are submitted online via the [Risk & Safety Solutions \(RSS\) Platform](#). RSS requires a UCInetID to login.
2. The deadline for submittal is typically the 3 weeks prior to the scheduled date of the IBC meeting.
3. Projects are initially reviewed by the EHS Biosafety staff and assigned an appropriate biological safety level (BSL) and work practices following a thorough risk assessment.
4. Review by the IBC occurs on the third Wednesday of each month, except November and December
5. Communication of the IBC decision to the PI via email or system notification within three days after the meeting date.

Description of IBC Protocol Review Outcomes

Approved

The IBC discussed the protocol and had no significant comments or concerns. Approval is valid for the study as described in the protocol for a period of three years from the approval date.

Tabled Administratively

Minor details, corrections, or confirmations are required. The PI must respond in writing to the issues and make corrections as requested. The protocol will be reviewed administratively and can be approved by the Chair without returning to the full committee.

Tabled to Subcommittee

The investigator's response will be reviewed by a subcommittee that may approve the protocol without returning to the full committee. The investigator must respond in writing to the IBC's letter. The **response will be reviewed by the primary and secondary reviewers** of the protocol.

Resubmission Required

A response to the IBC's concerns must be submitted as a new protocol for full committee review at a convened meeting.

5.2 BIOSAFETY CONTAINMENT LEVELS FOR BIOLOGICAL RESEARCH INVOLVING POTENTIAL BIOHAZARDS

BIOSAFETY LEVELS (BSL)	BSL1	BSL2	BSL2+	BSL3
A. HAZARD LEVELS				
<i>Degree of hazard</i>	Low Risk agents. e.g.: non-pathogenic agents, E. coli K-12, B strains, mouse cell cultures,	Low to Moderate risk; Herpes viruses, Foodborne Pathogens: Salmonella, Shigella, pathogenic E.coli	Moderate to High: HIV in small quantities, some influenza viruses, large varieties of bacteria where contamination is a concern	High risk pathogens of public health concern, high risk aerosol transmission: M. tuberculosis, SARS-Cov-2, etc.
B. STANDARD MICROBIOLOGICAL PRACTICES¹				
1. Public access while experiments are in process	Not recommended	Access to the lab is limited when BSL2 work is being conducted	Restricted	Not permitted
2. Decontamination Frequency	Daily & upon spills	Daily, upon finished work with biohazardous materials & spills	Daily, upon finished work with biohazardous materials & spills	Daily, upon finished work & spills
3. Biohazardous waste decontamination	Non-rDNA waste autoclaved or chemically disinfected, then dispose in regular trash; rDNA waste must be pickup by EHS	Pickup by EHS		Autoclave, then removal from lab by EHS
4. Pipetting	Mechanical device			
¹ . Standard microbiological practices are based on the current version of the CDC Biosafety in Microbiological and Biomedical Laboratories				

BIOSAFETY LEVELS (BSL)	BSL1	BSL2	BSL2+	BSL3
5. Eating, drinking, application of cosmetics or contact lenses	Permitted only in designated clean areas	Permitted only in designated clean areas	Not permitted	Not permitted
6. Handwashing facilities	Required		Required (foot/elbow/electronic operation recommended)	Required (foot/elbow/electronic operation)
7. Aerosol minimization procedures	Required			

C. CONTAINMENT EQUIPMENT

1. Biological Safety Cabinet (BSC)	Not required	Required for all aerosol generating processes	Required for all work with biohazardous agents	Required for all work
2. Other physical containment	Equipment must be decontaminated immediately after use	Physical containment devices, such as centrifuge safety cups, sealed centrifuge rotors and containment caging for animals are used for all activities with biohazardous materials that pose a threat of aerosol exposure. Equipment must be decontaminated immediately after use		
3. Freezers/ refrigerators	No biohazard sign required	Biohazard sign must be posted, and containers must be labeled		
4. BSC Certification	Recommended certified annually	Certified annually		
5. HEPA-filtered vacuum lines	Required			
6. BSC work surface decontamination	Daily & following spills	Required before and after each use		
7. Personal Protective Equipment (PPE)	Standard Lab PPE per UCI Policy.	Standard Lab PPE per UCI Policy. Plus, additional special protective clothing used as appropriate.	Facility and Agent Specific as determined by risk assessment. Respiratory Protection is typically required	
8. Laboratory coats	Standard Lab PPE		Fluid resistant with no front openings	Required (wrap around disposable clothing)

BIOSAFETY LEVELS (BSL)	BSL1	BSL2	BSL2+	BSL3
D. LABORATORY FACILITIES				
1. Ventilation	Negative pressure recommended; no recirculation of air to other areas of the building		Negative pressure; Air flows from low hazard to higher hazard areas; no recirculation of air is permitted	Negative pressure; no recirculation of air to other areas of the building.
2. Posted biohazardous material/ biosafety level signs	Not required	Required on lab doors in areas where biohazardous materials are stored and where work is done		
3. Bench top work	Permitted	Permitted for procedures with a low- risk of aerosol production	Not permitted	
4. Operable windows	Permitted with fly screens		Not permitted	

BIOSAFETY LEVELS (BSL)	BSL1	BSL2	BSL2+	BSL3
5. Laboratory separated from the general public	No. Doors must be closed and secure.		Yes. Doors must be closed and secure	Yes. Doors must be closed, and access is restricted to approved personnel only
F. OTHER REQUIREMENTS				
1. Technical Training	Agent / material specific training in addition to standard Lab Safety and Biosafety Trainings			
2. Medical Surveillance	Required when appropriate		Required to be offered	
3. Spill/accidents	Report immediately to lab director; medical evaluation, surveillance and treatment are provided as appropriate; maintain written records. The Biosafety Officer (BSO) must be notified at 949 824- 6200. BSO to notify the IBC.			
4. Biosafety manual	Personnel must have access to Biosafety Manual; personnel required to be familiar with policies & procedures.			Personnel must have access to Biosafety Manual; Specific BSL-3 Manual prepared or adopted; personnel are required to be familiar with policies & procedures.

UCI MEDICAL TREATMENT

5.3 UCI MEDICAL TREATMENT

For any immediate or life-threatening injuries, call 911.

Newport Urgent Care (949) 752-6300
Off-campus
1000 Bristol Street North, Suite 1-B
Newport Beach, CA 92660

Monday through Friday: 8:00AM to 9:00PM
Saturday and Sunday: 8:00AM to 8:00PM
After Hours: Call Newport Urgent Care for after-hours physician or go to any emergency room

Services provided to Newport Urgent Care to graduate or undergraduate students will be charged to their insurance (private, GSHIP, or USHIP). Please retain proof of visit and potential reimbursement.

5.4 FOR MEDICAL AUTHORIZATION

During work hours: UCI Workers' Compensation (949) 824-9152 or (949) 824-0500
When Workers' Compensation is unavailable, the employee's supervisor may grant authorization

5.5 ALTERNATE LOCATIONS

5.5.1 STUDENT HEALTH CENTER (949) 824-5304

East Peltason and Pereira
Monday through Friday: 7:30AM to 5:30PM
First aid treatment only
Graduate and undergraduate students only

5.5.2 OCCUPATIONAL HEALTH CLINIC (714) 456-8300

UCI Medical Center Pavilion III, Building 29
Monday through Friday: 7:30AM to 5:30PM

5.5.3 KAISER OCCUPATIONAL HEALTH CENTER

Off-campus
Irvine, (949) 932-5899
Santa Ana, (714) 830-6660

5.5.4 MEMORIAL OCCUPATIONAL MEDICAL SERVICES (562) 933-0085

Off-campus
Located at Long Beach Memorial Hospital

5.13.1 INSECT/RODENT CONTROL PLAN

UC Irvine Facilities Management provides a professionally engineered preventative pest management program to all state funded buildings. The first program consists of performing detailed applications around the exterior of buildings. Efforts are designed to maintain control of "crawling" pests, such as ants, spiders etc. Facilities Management also provides a professionally engineered rodent control program, with the objective to achieve, then maintain control of any existing or potential rodent population.

Facilities Management regularly inspects and closely monitors the area for any rodent activity or conditions that would be conducive to a rodent population. If evidence of any insect or rodent activity is found, Facilities Management will take the necessary steps to correct the situation. For more information, contact the Integrated Pest Management section of Facilities Management at (949) 824-5444.

5.12 LABORATORY EQUIPMENT

5.12.1 BIOSAFETY CABINETS

Biological safety cabinets (BSC) are used to prevent the escape of aerosols or droplets and to protect the research product from airborne contamination.

Types of Biosafety Cabinets

There are three major classes of biosafety cabinets:

- Class I – The IBC discourages the use of Class I BSCs at UCI. Talk to the UCI Biosafety Officer prior to using a Class I BSC to obtain approval.
- Class II (Type A1, Type A2, and Type A/B3) – This is the most common class of BSCs found on campus.
- Class III

Type	Face velocity (lfpm)	Airflow Pattern	Radionuclides/ Toxic Chemicals	Biosafety Level(s)	Product Protection
Class I* open front	75	In at front; rear and top through HEPA filter	No	2,3	No
Class II Type A1	75	70% recirculated through HEPA; exhaust through HEPA	No	2,3	Yes
Type A2 or A/B3	100	70% recirculated through HEPA; exhaust through HEPA that can be ducted	Yes (Low levels/volatility) when ducted	2,3	Yes
Type B1	100	30% recirculated through HEPA; exhaust via HEPA and hard ducted	Yes (Low levels/volatility)	2,3	Yes
Type B2	100	No recirculation; total exhaust via HEPA and hard ducted	Yes	2,3	Yes
Class III	NA	Supply air inlets and exhaust through 2 HEPA filters	Yes	3,4	Yes

*Glove panels may be added and will increase face velocity to 150 lfpm; gloves may be added with an inlet air pressure release that will allow work with chemicals/radionuclides.

Certification, Maintenance and Repair

It is the PI's responsibility to ensure that all biological safety cabinets used for handling biohazardous materials are certified when installed, moved between buildings, and recertified annually. Certification must be completed by an NSF Accredited Biosafety Cabinet Field Technician.

AUTOCLAVES

Autoclaving to render the waste noninfectious is the primary method used at UCI to treat biohazardous waste before disposal. Operating procedures for steam sterilizers must include, but not be limited to, the following:

- Adoption of standard written operating procedures for each steam sterilizer, including time, temperature, pressure, type of waste, type of container(s), closure on container(s), pattern of loading, water content and maximum load quantity.
- Check of recording and/or indicating thermometers during each complete cycle to ensure the attainment of a temperature of 121°C (250°F) for one-half hour or longer, depending on quantity and compaction of the load, in order to achieve sterilization of the entire load. Thermometers shall be checked for calibration at least annually.
- Prepared under standard operating conditions, use of the biological indicator *Bacillus stearothermophilus* placed at the center of a load at least monthly to confirm the attainment of adequate sterilization condition.
- Maintenance of records of procedures specified in 1, 2 and 3 above for a period of not less than three years. Maintain a log of the autoclave operation.
- Training by EHS.

CENTRIFUGES

Hazards associated with centrifuging include mechanical failure (e.g., rotor failure, tube, or bucket failure) and the creation of aerosols. To minimize the risk of mechanical failure, centrifuges must be maintained and used according to the manufacturer's instructions. Users should be properly trained, and operating instructions that include safety precautions should be prominently posted on the unit.

To minimize the generation of aerosols when centrifuging biohazardous material, the following procedures should be followed:

- Use sealed tubes and safety buckets that seal with O-rings. Before use, inspect all equipment for cracks, chips, etc.
- Fill and open centrifuge tubes, rotors, and accessories in a BSC.
- Do not decant or pour off supernatant. Use a vacuum system with appropriate in-line reservoirs and HEPA filters.
- Small low-speed centrifuges may be placed in a BSC during use to reduce aerosol escape.
- Avoid use of celluloid (cellulose nitrate) tubes with biohazardous materials. They are highly flammable and prone to shrinkage. They distort on boiling and can be highly explosive in an autoclave. If they must be used, decontaminate with an appropriate disinfectant.

OTHER AEROSOL GENERATING EQUIPMENT

The use of blenders, ultrasonic disrupters, grinders, and lyophilizers can result in considerable aerosol production. This equipment should be used in a BSC when working with biohazardous materials.

- Safety blenders are designed to prevent leakage from the bottom of the blender jar, provide a cooling jacket to avoid biological inactivation and to withstand sterilization by autoclaving. If blender rotors are not leakproof, they should be tested with sterile saline or dye solution prior to use with biohazardous material. The use of glass blender jars is not recommended because of the breakage potential. If they must be used, glass jars should be covered with a polypropylene jar to prevent spraying of glass and contents in the event the blender jar breaks. A towel moistened with disinfectant should be placed over the top of the blender during use. Before opening the blender jar, allow the unit to rest for at least one minute to allow the aerosol to settle and then open in a BSC. The device should be decontaminated promptly after use.
- Lyophilizers and ampoules: Depending on lyophilizer design, aerosol production may occur when material is loaded or removed from the lyophilizer unit. If possible, sample material should be loaded in a BSC. The vacuum pump exhaust should be filtered to remove any hazardous agents or, alternatively, the pump can be vented into a BSC. After lyophilization is completed, all surfaces of the unit that have been exposed to the agent should be disinfected. If the lyophilizer is equipped with a removable chamber, it should be closed off and moved to a BSC for unloading and decontamination. Handling of cultures should be minimized, and vapor traps should be used wherever possible.
- Opening ampoules containing liquid or lyophilized culture material should be performed in a BSC to control the aerosol produced. Gloves must be worn. To open, nick the neck of the ampoule with a file. Wrap it in a disinfectant soaked towel. Hold the ampoule upright and snap it open at the nick. Reconstitute the contents of the ampoule by slowly adding liquid against the side of container to avoid aerosolization of the dried material. Mix the contents

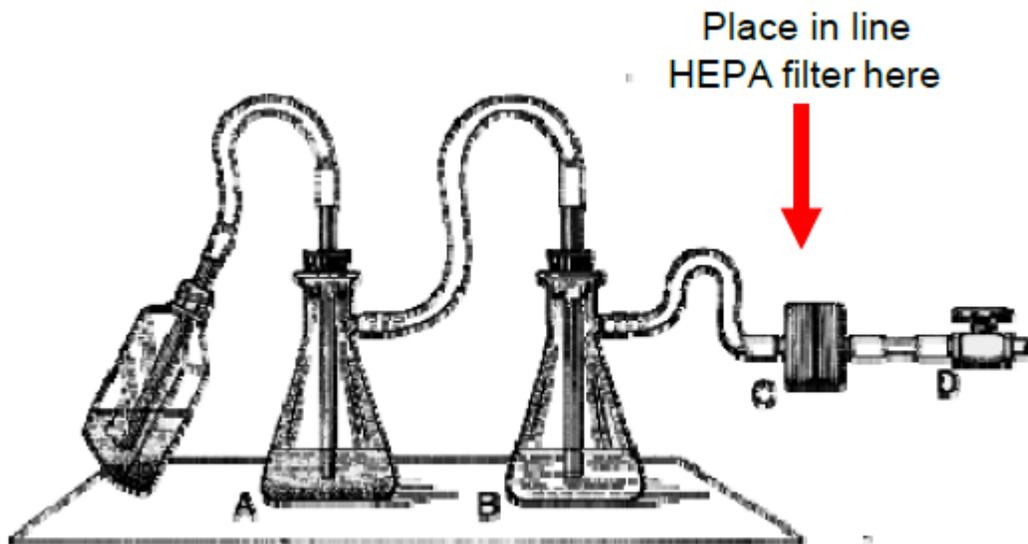
without bubbling and withdraw it into a fresh container. Discard the towel and ampoule top and bottom as biohazardous material waste.

VACUUM SYSTEMS

One method to protect a house vacuum system during aspiration of infectious fluids can be seen below. The left suction flask (A) is used to collect the contaminated fluids into a suitable decontamination solution; the right flask serves as a fluid overflow collection vessel. Flask B is used to minimize splatter. An in-line HEPA filter

(C) is used to protect the vacuum system (D) from aerosolized microorganisms.

If a glass flask is used at floor level, place it in a plastic container that is large enough to contain any spilled liquid to prevent breakage by accidental kicking. Do not use absorbable material, such as cardboard or Styrofoam, as a secondary container. In BSL2 or higher laboratories, the use of Nalgene flasks is recommended to reduce the risk of breakage.



5.13 BIOHAZARDOUS MATERIAL SPILLS

5.13.1 BIOHAZARD SPILL CLEANUP PROCEDURES

1. Notify everyone in the lab.
2. If a spill contains BSL2 or greater containment material, or if the spill is considered too large or too dangerous for laboratory personnel to safely clean up, secure the area including the whole lab and call EHS immediately for assistance. Only trained personnel should be cleaning up spills.
 - If after hours, call UCI Police Department at 911.
3. Wear a lab coat, gloves, and safety glasses.
4. Contain the spill and clear area. Use signs if necessary to caution others to stay away.
5. Disinfect the spill material. Remove sharps using tools such as tongs.
6. Place absorbent material on contaminated surface and pour disinfectant (i.e., freshly made 10% bleach), working from the outside of the spill towards the center until the absorbent material is soaked with disinfectant.
7. Leave the disinfectant to soak for at least 20 minutes.
8. Disinfectant can be absorbed with paper towels. A final wipe down should be done with clean paper towels soaked with disinfectant.

9. Place paper towels and disposable PPE into plastic, red biohazard bags and if appropriate, sharps waste container. Contaminated clothing should be placed into bags labeled as biohazardous autoclaved, and commercially laundered.
10. Wash hands thoroughly with soap and water.
11. Report incident to lab supervisor and contact EHS.

Considerations

- Protect yourself by avoiding direct contact with spilled material, treating material as if it is infectious, and wear appropriate PPE. An N95 respirator is advised for spills greater than ~10mL outside a BSC, or any spill inside a centrifuge.
- Alcohol is not recommended as a disinfectant for large spills, especially inside a BSC, because large amounts of alcohol pose an explosion hazard.
- For spills inside a BSC, wait 20 minutes for BSC to contain aerosols and wipe all surfaces (including walls and sash). Expose non-autoclavable materials to 10% bleach solution for 20 minute before removal from BSC. Run BSC for 20 minutes after clean up.

5.14 DECONTAMINATION AND DISINFECTION

5.14.1 GENERAL GUIDELINES

- A. All infectious materials and all contaminated equipment or apparatus should be decontaminated before being washed stored or discarded. Each individual working with biohazardous material should be responsible for its proper handling and disposal.
- B. Dry hypochlorites, or any other strong oxidizing material, must not be autoclaved with organic materials such as paper, cloth, or oil. **Oxidizer + Organic Material + Heat = may produce an explosion.**
- C. Liquid, gas or vapor disinfectants, dry heat, ultraviolet or ionizing radiation appropriate for some applications may not substitute for autoclaving or incineration before disposal.
- D. Although some chemicals may be utilized as either a disinfectant or an antiseptic, adequacy for one application does not guarantee adequacy for the other.

5.14.2 METHODS

There are four main categories of physical and chemical means of decontamination: (1) heat; (2) liquid disinfection; (3) vapors and gases; and (4) radiation. More information on decontamination can be found in the Biosafety in Microbiological and Biomedical Laboratories [BMBL](#).

5.15 HANDLING BIOHAZARDOUS AND MEDICAL WASTE

All PIs and lab personnel generating waste are required to complete the Hazardous Waste Training on the [UCLC website](#).

5.15.1 BIOHAZARDOUS WASTE

- Laboratory waste including specimen cultures from medical and pathological laboratories; cultures and stocks of biohazardous materials from research, clinical and teaching laboratories; wastes from the production of biological agents; discarded live and attenuated vaccines; and culture dishes and devices used to transfer, inoculate, and mix cultures or material which may contain any biohazards.

- Human blood (including articles contaminated with blood), components of blood or body fluids such as cerebrospinal fluid, synovial fluids, pleural fluid, peritoneal fluid, pericardial fluid, and amniotic fluid. An exception to this is when the body fluid contaminant will dry within a couple of hours and does not have enough liquid phase to drip from the article, that contaminated article may be treated as medical solid waste.
- Any human or primate tissue.
- Sharps [objects or devices having acute rigid corners, edges, or protuberances capable of cutting or piercing - including glass pipettes (small and large), hypodermic needles, blades, slides, and broken glass].
- Any specimens sent to a laboratory for microbiologic analysis.
- Surgical specimens including human, or primate animal parts or tissues removed surgically or by autopsy.
- Such other waste materials that result from the administration of medical care to a patient by health care providers and are found by the administering agency or the local Health Officer to pose a threat to human health or the environment.
- Surgical specimens including human, or primate animal parts or tissues removed surgically or by autopsy.

NOT ALL BIOHAZARDOUS WASTE ARE MEDICAL WASTE.

Medical Waste

The Medical Waste Management Act defines “**medical waste**” as biohazardous or sharps waste and waste which is generated or produced as a result of the diagnosis, treatment, or immunization of human beings/animals, research pertaining to the diagnosis, treatment, or immunization of human beings/animals, production/testing of biologicals, or the accumulation of properly contained home-generated sharps waste.

California Medical Waste Management Act

To protect the public and the environment from potentially infectious disease-causing agents, the Medical Waste Management Program (MWMP) regulates the generation, handling, storage, treatment, and disposal of medical waste by providing oversight for the implementation of the Medical Waste Management Act (MWMA).

UCI’s [Medical Waste Management Plan](#) can be found on the EHS website.

All labs operating at Biosafety Level-2 using human or primate cells, cell lines, tissues, or body fluids, or infectious agents or BSL-3 labs must dispose of materials as medical waste.

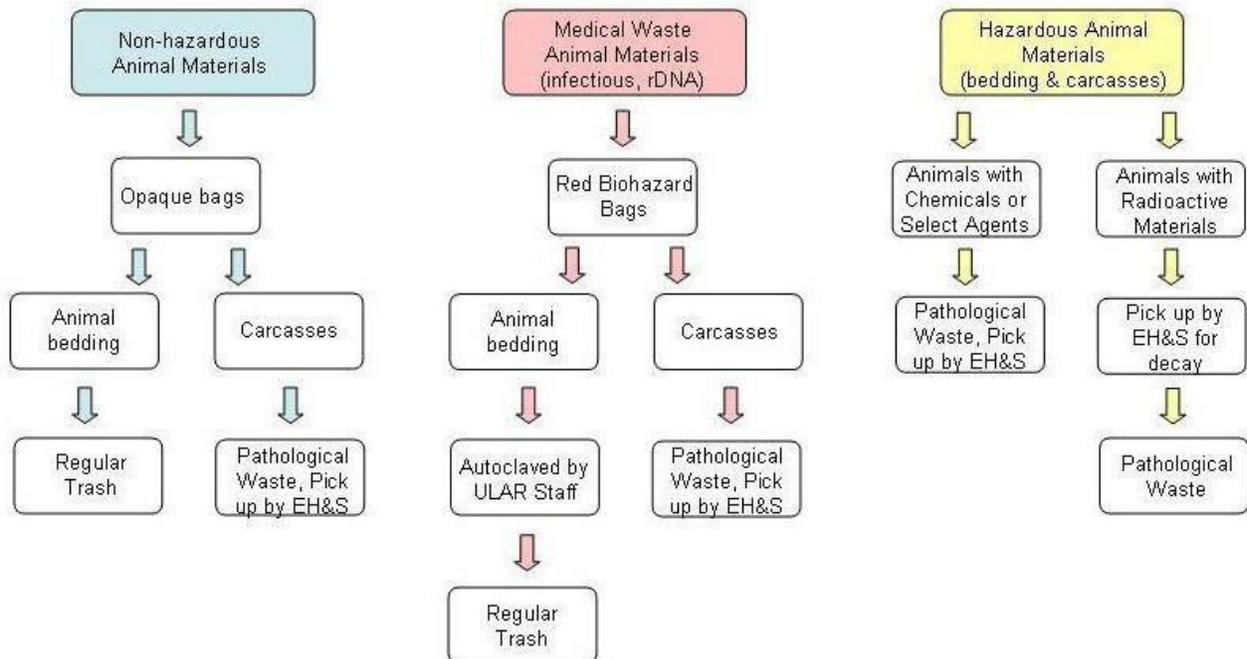
Guidelines for Solid Waste:

1. Insert a bag inside a rigid container and fold the edges over the lip of the container. Insert second bag so that waste is doubled-bagged. All waste containers should be marked with “Biohazardous Waste” or with the biohazard symbol.
 - For BSL-1 waste, use a white or clear biohazard bag.
 - For medical waste, use a red biohazard bag marked and certified with ASTM D1922 and ASTM D1709. Orange bags are illegal to use in California.
 - For sharps waste, place sharps (e.g., needles, glass pipettes, blades) in rigid, puncture-resistant, tamper-proof containers.
 - Recognizable human anatomical specimens or tissues require special disposal. Contact biosafety@uci.edu for more information.
 - All animal carcasses on campus are treated as pathological waste. More information is shown in the flowchart below.
2. Keep a lid on the biohazardous materials waste container except when in use.

3. When the container is one-half to two-thirds full, close and tie off the inside bag, and then close and tie off the exterior bag. Remove the bag the from container and place autoclave tape on it.
4. Transport of biohazardous waste must be placed inside a secondary container that is rigid, leak-proof container with a leak- proof lid. Decontaminate the outside of the secondary container prior to transport.
5. Storage for untreated, bagged biohazardous waste must be secured to deny access to unauthorized personnel. Maximum storage is 7 days or less when stored above the temperature 32° F OR 90 days or less when stored below 0°C.
6. Disposal of:
 - For BSL-1 waste (non-recombinant DNA), autoclave or chemically disinfect prior to disposing in municipal trash.
 - For medical waste, pathological, and sharps waste, contact EHS for pick-up. More information on pick-up can be found on [Hazardous Waste webpage](#).

Other Waste Considerations:

- Biohazard bags and sharps containers can be obtained from UCI EHS at (949) 824-6200.
- Liquid waste can be discharged into approved sewer systems after decontamination. Chemicals other than bleach may not be poured into the sewer.
- Biological waste mixed with chemicals or radiological waste should be treated as chemical or radiological waste, respectively.



5.16 LABORATORY INSPECTION

5.16.1 REGULATORY AGENCY INSPECTION

Notify EHS at (949) 824-6200 if a regulatory agency official attempts to inspect your laboratory. No laboratory may be inspected by such officials without the EHS management's full knowledge and the participation of an EHS representative.

5.16.2 BIOSAFETY INSPECTIONS

Biosafety inspections occur for new labs, when the lab biohazard risk profile changes, per IBC request on and when lab's shut down/inactivate a BUA. Annual Laboratory Safety Inspections are conducted by UCI EHS.

5.17 INFECTIOUS AGENT AND BIOHAZARDOUS MATERIAL SHIPPING PROGRAM DESCRIPTION

It is a requirement of UCI that anyone shipping dangerous goods (such as infectious agents, biological materials, diagnostic specimens, Select Agents, chemical or radioactive materials) is required to receive special training on the Shipment of Dangerous Goods or the materials must be packaged by Environmental Health and Safety (EHS) or personnel within the school who are trained specifically to package these materials. For questions, please contact EHS at (949) 824-6200.

5.17.1 SCOPE OF PROGRAM

The Department of Transportation (DOT) Hazardous Materials Shipping Regulations (49 CFR) apply to anyone packaging or shipping Hazardous Materials by ground transportation.

The International Air Transport Association Dangerous Goods Regulations apply to anyone packaging or shipping Dangerous Goods by air transport (any package which is offered to a major commercial carrier should be packaged for air transport).

The University of California, Irvine policy applies to any UCI employee that packages hazardous materials or dangerous goods for shipment.

5.17.2 DEFINITIONS

Infectious Substance (Division 6.2) means a material known to contain or suspected of containing a pathogen that has the potential to cause disease in humans or animals if exposure to it occurs. Pathogens are micro-organisms (including bacteria, viruses, rickettsia, parasites, and fungi) or recombinant micro-organisms (hybrid or mutant) that cause infectious disease in humans or animals. A Division 6.2 material must be assigned to a risk group. Assignment of a UN number is based on known medical condition and history of the source patient or animal, endemic local conditions, symptoms of the source patient or animal, or professional judgment concerning individual circumstances of the source patient or animal.

Cultures and stocks mean a material that is prepared and maintained for growth and storage and that contains a Risk Group 2, 3 or 4 infectious substance.

Diagnostic specimen means any human or animal material, including excreta, secretions, blood and its components, tissue, and tissue fluids being transported for diagnostic or investigational purposes, but excluding live infected humans or animals. A diagnostic specimen is not assigned a UN identification number unless the source patient or animal has or may have a serious human or animal disease from a Risk Group 4 micro-organism. Assignment of a UN number is based on known medical condition and history of the patient or animal, endemic local conditions, symptoms of the source patient or animal, or professional judgment concerning individual circumstances of the source patient or animal.

Genetically Modified Microorganisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally.

Risk group means a ranking of a micro-organism's ability to cause injury through disease. A risk group is defined by criteria developed by the NIH based on the pathogenicity of the organism, the mode and relative ease of transmission, the degree of risk to both an individual and a community, and the reversibility of the disease through the availability of known and effective preventative agents and treatment. There is no relationship between a risk group and a packing group.

Toxin means a Division 6.1 material secreted from a plant, animal, or bacterial source.

Dangerous Goods/Hazardous Materials (HAZMAT) - Articles or substances which can pose a significant risk to health, safety or property when transported.

HAZMAT Employee - Definition from 49 CFR (171.8) means a person who is employed by a hazmat employer and who in the course of employment directly affects hazardous materials transportation safety. This term includes an owner- operator of a motor vehicle which transports hazardous materials in commerce. This term also includes an individual, employed by a hazmat employer who, during the course of employment:

- loads, unloads, or handles hazardous materials;
- manufactures, tests, reconditions, repairs, modifies, marks, or otherwise represents containers, drums, or packaging as qualified for use in the transportation of hazardous materials;
- prepares hazardous materials for transportation;
- is responsible for safety of transporting hazardous materials;
- operates a vehicle to transport hazardous materials.

HAZMAT Employer - Definition from 49 CFR (171.8) means a person who uses one or more of its employees in connection with: transporting hazardous materials in commerce; causing hazardous materials to be shipped in commerce; or repairing, or modifying containers, drums, or packages as qualifying for use in the transportation of hazardous materials. This term includes an owner-operator of a motor vehicle which transports hazardous materials in commerce. This term also includes any department, agency, or instrumentality of the United States, a State, a political subdivision of a State, or an Indian tribe engaged in an activity described in the first sentence of this paragraph.

IATA - International Air Transport Association. Comprised of member international airlines which establish regulations for uniform safety and interline exchange. For

Initial - Programs designed for both first-time users and for those whose certification has expired. Both international and United States law dictates that anyone with an expired dangerous goods certification must enroll in Initial certification programs.

Initial programs cover introduction to the applicable regulations to full certification for job specific training.

5.17.3 RESPONSIBILITIES REQUIREMENTS FOR ALL DANGEROUS GOODS SHIPMENTS

All of the following requirements must be met prior to shipment of Dangerous Goods:

- The Shipper must receive training in shipping dangerous goods. Shippers are directly responsible for the correct and legal transport of dangerous goods by surface or air. Anyone who offers advice for transport, transports, or handles hazardous materials for transport must be trained (49 CFR Part 172- Subpart H).
- The Shipper must use UN approved labels and packages.
- The Shipper must apply for Import or Export permits if needed.
- The Shipper must complete shipping documentation (2 copies, typewritten or computer generated) (Shipper's Declaration for Dangerous Goods).
- The Shipper must attach information to the Shipper's Declaration for Dangerous Goods stating the hazards associated with the shipment (i.e., Material Safety Data Sheets).
- The Shipper must have a 24-hour Emergency Phone Number with information available about the shipment.
- CHEMTREC: 1-800-424-9300 (24-hour emergency number).

- UC Irvine is authorized to use the CHEMTREC toll-free, 24-hour emergency telephone number for shipments of hazardous materials. Please use the CHEMTREC number as your "emergency contact number" when completing the shippers declaration for dangerous goods, under the Additional Handling Information section. A copy of the shipping paperwork must be faxed to CHEMTREC, and a copy must be faxed to EHS at (949) 824-8539 prior to shipment.
- The Shipper must retain copies of shipping papers for a minimum 375 days.
- It is the responsibility of EHS to assist in the oversight of packaging and shipping hazardous materials and dangerous goods by the shipper.

5.17.4 SPECIFIC PROGRAM COMPONENTS

Shipping requirements for Biohazardous Materials, Diagnostic Specimens, or Infectious Agents

Material to be shipped	How material will be shipped	Requirements	Contact
<ul style="list-style-type: none"> • Infectious substances • Cultures and stocks • Toxins • Genetically modified micro-organisms 	Shipment by air, including all Federal Express shipments	Complete training every 2 years or any time regulations changed	Biosafety Officer
<ul style="list-style-type: none"> • CDC Select Agents* • USDA Consequence Pathogens* 		Prior to both shipping and receiving	EHS High Containment Director or Biosafety Officer
<ul style="list-style-type: none"> • Insects 		Potentially USDA APHIS permit	Biosafety Officer
<ul style="list-style-type: none"> • Etiologic agents imported from foreign countries 		US Public Health Service importation permit	Biosafety Officer
<ul style="list-style-type: none"> • Animals and animal-derived materials from foreign countries 		<ul style="list-style-type: none"> • USDA • APHIS Import Authorization System. • Veterinary Services (VS) • CDC Importation Permit Application. 	

5.17.5 REPORTING REQUIREMENTS

Please contact EHS at least one week prior to the shipment date of the material to ensure that the shipment will reach its destination in a timely manner at (949) 824- 6200. The Shipper must retain copies of shipping papers for a minimum 375 days after the shipment is completed.

5.17.6 INFORMATION AND EXTERNAL SOURCES

- [DOT's Office of Hazardous Materials Safety](#): (800) 467-4922 For assistance [classifying shipments](#)
- [FedEx Dangerous Goods Hotline](#): (800) 463-3339 then press "81" to be connected to the Dangerous Goods/Hazardous Materials Hotline
- [International Air Transport Association](#) (IATA) Dangerous Goods Hotline: (514) 390-6770
- [UPS Guide for Transporting Hazardous Materials](#)
UPS Hazardous Materials Support Center (800) 554-9964

5.17.7 COMPETENCY AND TRAINING REQUIREMENTS

Recurrent Training - Programs designed for those needing recertification and still holding a current dangerous goods certification. Current law states that certification is valid for 24 months for IATA, except air carriers must

be certified annually. United States law states recurrent training must take place within 3 years (applicable to 49 CFR and IMDG) or as often as the regulations change, whichever is sooner.

For more information pertaining to proper shipping and packaging of etiologic agents visit the EHS website at <https://ehs.uci.edu/> or contact the UCI EHS at (949) 824-6200.

PIs and lab personnel who ship dangerous and hazardous materials are required to take the Shipping Hazardous Materials Training on the [UCLC website](#).

5.17.8 SHIPPING DANGEROUS AND HAZARDOUS MATERIALS

For more information regarding the shipping of dangerous or hazardous materials contact the UCI EHS at (949) 824-6200.

5.17.9 SUSPICIOUS PACKAGES

For guidance on handling suspicious packages contact UCI EHS at (949) 824-6200.

5.18 DHHS-CDC SELECT AGENT AND USDA HIGH CONSEQUENCE LIVESTOCK PATHOGENS

The Department of Health and Human Services, Centers for Disease Control and Prevention (DHHS-CDC) Select Agent Rule (also known as “The Anti-Terrorism and Effective Death Penalty Act of 1996”) initially tracked the transfer of Select Agents including bacteria, viruses, fungi, and biological toxins due to their potential use as bioterrorist weapons.

The PATRIOT Act of 2001 requires personnel with access to Select Agents or High Consequence Livestock Pathogens requiring registration to have a background check performed by the Department of Justice prior to performing research with registered Select Agents.

In December 2002, the Select Agent Rule was modified as a part of the Public Health and Security and Bioterrorism Preparedness and Response Act of 2002, to include possession and use of Select Agents and the list was expanded to incorporate the US Department of Agriculture (USDA) High Consequence Livestock Pathogens.

Select Agents and Toxins Overview: <http://www.selectagents.gov/>

[List of CDC/USDA Select Agents and Toxins \(and USDA High Consequence Livestock Pathogens\)](#)

PIs and lab personnel handling select agents and/or toxins are required to take the Select Agent and Toxins Training on the [UCLC website](#).

5.18.1 EXEMPTIONS FROM CDC SELECT AGENTS AND TOXINS RULE

Labs with more than the exempt quantities of Biological Toxins and any amount of Select agent are required to register with CDC and/or USDA and meet all requirements for biosafety, biosecurity, incident response plan and training required by the Federal Select Agent Program and UCI Select Agent and Toxins Policy. Labs that work with attenuated strain of a select biological agent or toxin that does not pose a severe threat to public health and safety, animal health, or animal products may be excluded from the requirements of the select agent regulations. Please review the [Select Agents and Toxins Exclusions](#) as some select toxins are exempt based on the total amount that the lab will possess at any time.

If your lab has exempt quantities of Select Toxins and is using exempt select biological agent or toxin, you must register with IBC by completing an IBC application. You are required to perform a quarterly inventory of Select Toxins and your facility must meet minimum security requirements. UCI EHS will carry out both the annual inventory of the exempt Select Toxin and a walkthrough of locations where the exempt select toxin is used. Also, your laboratory must have Select Agent and Toxin specific standard operating procedures (SOPs). SOPs will be provided by the UCI Biosafety Officer for Select Toxins use at UCI. All personnel must be trained annually on lab specific SOP and UCI Select Agent training.

Medical use of toxins for patient treatment is exempt

If the aggregate amounts are exempt:

If the aggregate amounts of the following agents or toxins under the control of a principal investigator do not, at any time, exceed the limits set by CDC/USDA, they are exempt from FSAP regulation.

Check the Federal Select Agent website for the most current list of exempt quantity amounts.

<http://www.selectagents.gov/PermissibleToxinAmounts.html>

Other exempted agents and toxins are:

- Any agent or toxin that is in its naturally occurring environment provided it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.
- Non-viable Select Agent organisms or nonfunctional toxins.
- The vaccine strains of Junin virus (Candid #1), Rift Valley fever virus (MP-12), and Venezuelan Equine encephalitis virus vaccine strain TC-83 and [other attenuated strains](#).

5.18.2 CDC SELECT AGENT OR USDA HIGH CONSEQUENCE LIVESTOCK PATHOGENS REGISTRATION

CDC/USDA and UCI IBC registration and approval are required prior to receipt and use of Select Agent or Toxin at UCI.

5.18.3 TRANSFER OF CDC SELECT AGENTS OR USDA HIGH CONSEQUENCE LIVESTOCK PATHOGENS

The UCI Biosafety Officer must be notified prior to any transfer of Select Agent or any material containing Select Agents or Toxin. The UCI Responsible Official, (the Biosafety Officer) or the Alternative Responsible Official (the Associate Biosafety Officer) must sign the required forms for CDC prior to shipment of Select Agents, materials containing select agent and toxins.

5.18.4 TOXIN DUE DILIGENCE

Please review: <http://www.selectagents.gov/faq-diligence.html>

The "due diligence" provision applies to anyone (registered or unregistered individuals or entities) that transfers toxin listed under CFR [Section 73.3](#)

in amounts that otherwise would be excluded from the select agent regulations. The FSAP developed the provision to address the concern that someone might stockpile toxins by receiving multiple orders below the excluded amount. The "toxin due diligence" provision requires a person transferring toxins in amounts which would otherwise be excluded from the provisions to: (1) use due diligence to assure that the recipient has a legitimate need to handle or use such toxins; and (2) report to FSAP if they detect a known or suspected violation of Federal law or become aware of suspicious activity related to the toxin.

If you have any questions regarding the UCI Select Agent Policy, please contact the UCI Biosafety Officer at (949) 824-6200.

6.0 REPORTING REQUIREMENTS

An Emergency Response Guide Flipchart should be posted in each laboratory. The guide contains procedures for spills, exposures, incidents, reporting instructions, contact numbers, and the location of emergency equipment. PIs or a designated lab safety coordinator must review the guide with new personnel.

Report all injuries, accidents, animal bites, and exposures to your supervisor and complete the [EHS Accident Report Form \(Appendix A\)](#).

All incidents involving biological materials and agents included in the IBC application must be reported to the IBC at ibc@uci.edu, within 24 hours. If the incident falls under [NIH guidelines](#), the incident will be reported to the NIH.

6.1 TISSUE AND CELL CULTURE

6.1.1 HUMAN AND NON-HUMAN PRIMATE MATERIALS

The manipulation of human and non-human primate materials including blood, unfixed materials, established and immortalized cell lines places laboratory workers at risk due to potentially infectious agents that can reside in these materials. Due to this potential for exposure, materials of Old World Non-human primate origins (macaque species) must be treated as if they were known to be infectious.

Both human and non-human primate materials should be handled with BSL-2 practices and containment.

Human materials specifically fall under the OSHA Bloodborne Pathogens (BBP) Standard.

6.1.2 OSHA BBP Standard

All human cell lines are considered potentially infectious and fall under the OSHA BBP Standard unless pathogen testing, and clearance has been conducted and documented for a specific cell line. The purpose is to reduce occupational exposure to human bloodborne pathogens that may come in contact within the workplace, and to establish a framework for training and medical response.

If there is any possibility an employee may be exposed to BBP's during their work, the PI must do the following:

- Implement a written Exposure Control Plan (ECP) which adopts BSL2 or higher containment practices and procedures.
- Offer personnel with occupational exposure appropriate vaccination and retain a record thereof with the Hepatitis B declination form
- Require annual BBP Training. Training is completed and documented via the UCLC
- Update the ECP as needed, and at least annually.
- Register with the IBC if work is conducted with human blood, tissue, cells, and other body fluids.

PIs and lab personnel who work with BBP material are required to take the Bloodborne Pathogen Training on the [UCLC website](#).

6.1.3 OTHER CULTURED CELLS AND HARVESTED TISSUES

Other mammalian cell lines and tissues that are not of human or non-human primate origin, and do not contain known human or animal pathogens are designated as BSL-1. Cultured cells and any harvested tissues that have been administered or manipulated with an infectious agent (e.g., bacteria and viral based vector) are classified in the same biosafety level as the administered agent.

Under no circumstance shall anyone work with cells derived from themselves or from first- degree relatives since the host immune systems may not provide adequate protection.

PIs and lab personnel who work with viral vectors are required to take the Viral Vectors Training on the [UCLC website](#).

6.1.4 RESEARCH WITH HIV, HCV, AND HBV

Laboratory personnel (faculty and staff) in HIV, HCV or HBV research laboratories must fulfill additional requirements as follows:

- The employee must attend annual Bloodborne pathogens biosafety training offered by EHS.
- The employee must have prior experience in the handling of human pathogens or tissue cultures before working with HIV, HCV, or HBV.
- Before being allowed to work with HIV, HCV or HBV, the employee must demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the laboratory to the satisfaction of the Principal Investigator/laboratory supervisor.
- An employee with no prior experience in handling human pathogens must be trained in the laboratory prior to handling infectious materials. Initial work activities shall not include handling of infectious agents. A progression of work activities will be assigned as techniques are learned and proficiency is developed. Participation in work activities involving infectious agents will be allowed only after proficiency has been demonstrated to the satisfaction of the PI.

6.2 CONTAINMENT OF AEROSOL TRANSMISSIBLE DISEASES AND PATHOGENS

Aerosol transmissible diseases (ATD) or aerosol transmissible pathogens (ATP) are diseases or pathogens for which droplet or airborne precautions are required, as defined by the [Cal/OSHA ATD Standard](#). PIs with research involving any agent listed in Cal/OSHA ATP Standard – Laboratory must:

- Implement an ECP, which adopts BSL-2 or higher containment practices and procedures
- Perform and document the following:
 - Training
 - Medical services
 - Exposure incidents
 - Inspections
 - Evaluation of engineering controls and other control measures

PIs and lab personnel who work with ATD material are required to take the Aerosol Transmissible Disease Training on the [UCLC website](#).

If work requires respiratory protection, PIs and lab personnel are required to take the Respiratory Protection Training on the [UCLC website](#), in addition to being fitted for respiratory protection.

6.2.1 ZONOTIC ATPs

These are agents that are transmissible from animals to humans by aerosol and is capable of causing human disease. Zoonotic ATPs include pathogens that are classified as transmissible either by droplets or by an airborne route.

If working with sheep or goats, PIs and lab personnel are required to take Q Fever Training. Additional training may be required depending on what material is handled.

6.2.2 METHODS OF COMPLIANCE

The ATD Standard requires that all incoming materials containing ATPs-L are treated as containing the virulent or wild-type pathogens until there is laboratory verification that the pathogen has been deactivated or attenuated. This statement must be included in the Exposure Control Plan. Until the pathogenicity of the agent

has been verified, follow all appropriate biosafety practices and procedures for the virulent or wild-type pathogens.

Containment (e.g., biosafety cabinets, sealed centrifuge rotors or safety cups) that isolate or remove the hazard of ATPs from the workplace and, therefore, reduce the potential for employee exposure. Other devices include secondary transport containers and uni-directional airflow from areas of lower to areas of higher hazards.

6.2.3 MEDICAL SURVEILLANCE, VACCINATION & POST-EXPOSURE

The University (by means of funding provided by the department or PI, or EHS) must make any available vaccination available to those employees who have the potential for occupational exposure. Post-exposure evaluation and follow up must be provided to those employees who have had an exposure incident. This must be done at no cost to the employees and at a reasonable time and place. It must be performed under the supervision of a licensed physician or other licensed health care professional.

More information regarding medical surveillance, vaccinations and post-exposure evaluation, visit the [Occupational Health Program website](#).

HEPTATIS B (HBV) VACCINATION & POST-EXPOSURE

UCI (by means of funding provided by the department or PI or EHS) must make the HPV vaccination available to those employees who have the potential for occupational exposure. This must be available to the employee within 10 working days of initial assignment to work involving potential occupational exposure. Employees may decline to receive the vaccination. Should an employee (still covered under the Standard) who had previously declined decide later to receive the vaccination, it must be made available to him or her at no cost.

Post-exposure evaluation and follow up must be provided to those employees who have had an exposure incident. This must be done at no cost to the employees and at a reasonable time and place. It must be performed under the supervision of a licensed physician or other licensed health care professional.

Following a report of an exposure incident, the PI must make available to the exposed employee a confidential evaluation and follow up at no cost to the employee. This must include documentation of the route(s) and circumstances of the exposure incident; a testing* of the source individual's blood sample for HBV, HCV, and HIV (unless these are already known to be present in the source individual). Results of the source individual's blood sample test must be made available to the exposed employee, who must be informed of applicable laws.

Tuberculosis (TB) Assessments

Employees with occupational exposure will be offered assessment for latent tuberculosis infection (LTBI). Employees with TB positive baseline results are offered an annual symptom screen. If an employee experiences a TB conversion, they will be referred to a knowledgeable Physician or Other Licensed Health Care Professional (PLHCP) for evaluation and treatment. If the employee is a TB case or suspected case, the supervisor will request the physician or other licensed health care professional to do the following:

- Inform the employee and local health officer.
- Consult the local health officer regarding infection control recommendations.
- Provide a written recommendation for the employee to be removed from the workplace as a precaution until the employee is determined to be noninfectious (employee status will not be affected).

If an occupational TB conversion has occurred, the supervisor will work with the BSO to investigate the circumstances of the conversion and correct any deficiencies found during the investigation.

Medical Records

An Employee should provide either evidence of vaccination, immunity (titer results), or a Letter of Declination to their supervisor for their employee file.

Records must be confidential and may not be disclosed without the employee's written consent. Records must be kept for the duration of employment, and for at least 30 years after the last date of employment.

6.2.4 HAZARD COMMUNICATION

Labels

Fluorescent orange-red labels displaying the international biohazard symbol and the legend "biohazard" in contrasting colors are attached to containers of biohazardous materials.

Labeled red bags and labeled red containers are used for biohazardous waste and sharp containers. Fluorescent orange-red signs with lettering and symbols in contrasting colors are posted at entrances to work areas. Such signs specify special requirements for entering, name and telephone number of PI or other responsible person(s).

Labels can be obtained from UCI EHS at (949) 824-6200.

Signs

It's important that Principal Investigators, Lab Managers, and SOS Representatives keep their hazard emergency contact information current on the lab door posting. For more information on how to obtain hazard emergency notification door cards, contact your [school EHS coordinator](#).

Fluorescent orange-red labels displaying the international biohazard symbol and the legend "biohazard" or "biohazardous waste" in contrasting colors must be attached to containers of biohazards and biohazardous waste, respectively.



6.2.5 RECORDKEEPING

Availability of Records

Upon request, all records must be made available to the Chief of the Division of Occupational Safety and Health of the California Department of Industrial Relations, NIOSH or a designated representative for examination and copying.

In addition, training records must be made available to employees or employee's representative. Upon request, medical records may only be made available to the employee or to someone who has the employee's signed consent.

6.2.6 USE OF ANIMALS IN RESEARCH

The use of animals in research requires compliance with the Animal Welfare Act and any state or local regulations covering the care or use of animals. Facilities for laboratory animals used for studies of infectious or non-infectious disease should be physically separate from clinical laboratories and facilities that provide patient care.

Vertebrate animal biosafety level criteria must be adhered to where appropriate. All work with animals involving the use of rDNA and/or infectious or transmissible agents must be submitted to the IBC for review and approval in addition to approval from the Office of University Laboratory Animal Resources (ULAR) and Institutional Animal Care and Use Committee (IACUC).

The IBC may require the laboratory and the Biosafety Officer to work out specific details (e.g., animal handling, transportation, housing, waste disposal, etc.) prior to initiation of experiments requiring Animal Biosafety Level 2 or Animal Biosafety Level 3 containment. Investigators who are uncertain of how to categorize agents should call EHS at (949) 824-6200.

6.2.7 LABORATORY ANIMAL OCCUPATIONAL HEALTH PROGRAM (LAOHP)

Working with laboratory animals can present a risk to the health and well-being of research personnel, as well as other individuals that may have animal contact or exposure. Examples of health risks may include (a) zoonotic diseases (infectious agents shared by humans and animals); (b) allergies to laboratory animals, particularly rodents; (c) bites, scratches, and other injuries and (d) manipulation of hazardous materials in animals. The purpose of the Laboratory Animal Occupational Health Program (LAOHP) is to identify, evaluate, manage, and reduce potential health risks associated with the care and use of animals. By assessing an individual's risks, recommendations to prevent illness related to laboratory animal research can be made.

More information found on the [Laboratory Animal Occupational Health Program webpage](#).

6.2.8 DISPOSAL OF ANIMALS (CAMPUS OR UCIMC)

Animals used with infectious agents or transgenic animals must be disposed of through [EHS Hazardous Waste](#).

Please contact ULAR for the specific requirements for carcass disposal for your facility at (949) 824-4666.

6.2.9 ANIMAL ROOM SAFETY INFORMATION

Completion and posting of the Animal Room Hazard Communication and Biohazardous Animal Cage Card are required for all animal protocols involving use of hazardous materials

Lead Researcher is responsible for:

- placing the Animal Room Hazard Communication notice in the Hazard Communication folder at door of animal room when hazards are present;
- labeling the cages with the appropriate Biohazardous Animal Cage Cards;
- ensuring that an MSDS is available upon request; and
- creating a separate hazardous communication form for each hazardous agents listed in the IACUC protocol.

6.3 WHOLE BUILDING SAFETY

As laboratories are obviously just a portion of a whole building, the PI and lab workers should familiarize themselves with aspects of the building which are not necessarily restricted to their own labs, but which can impact their work or their neighbors' work. Included among such building issues are the following:

- Access
 - Doors must be kept closed while all BSL-2 or greater laboratories.
- Ventilation (including air supply, exhaust, and distribution)
 - It is the policy of the IBC that all work which requires BSL-2 or higher containment be conducted in laboratories which are negatively pressured with respect to their surroundings.
- Plumbing
 - Vacuum systems must be fitted with HEPA filters to prevent biohazardous materials from being sucked into the system.
- Emergency Equipment
 - Safety shower and eye wash
 - Fire Extinguisher

Any suspicious activity should be reported to UCI Police Department at (949) 824-5223. Any issue with access, ventilation, plumbing, or emergency equipment should be reported to Facilities Management.

Appendices

Appendix A: [EHS Accident Report Form](#)

Report an Injury, Safety Concern, Near-Miss, or COVID-19 Safety Concern

NOTE: If you are an employee of UCI Health, at any UCI Health site, you should make your report through the [UCI Health Safety and Quality Information System \(SQIS\)](#).

If you are a School of Medicine (SOM) employee working at any UCI Health location, please use this portal (campus) to report all injury/illnesses and near-misses.

Injuries, safety concerns, and/or COVID-19 concerns or near-misses occurring on campus or while participating in university business should be reported within 24 hours. For non-vehicle property damage ONLY, please see [HOW TO: Report Damaged or Destroyed Property](#).

If you or your employee experiences a serious injury that requires a trip to the hospital, please contact EHS immediately at [949-824-6200](#).

- During business hours, press 1 to be connected to the front desk.
- After hours and on weekends, press 2 to be connected to an EHS responder.

Please complete the following and click CONTINUE.

If more than one person was injured, please submit a report for each person.

1. Select the information that best describes the nature of the incident:

- Injury/illness - resulted from an incident.
- Safety Concern - unsafe condition or unsafe behavior.
- Near Miss - event that could have resulted in an injury/illness or caused property damage.

2. What is the affiliation of the person for whom this form is being completed?

- UC Irvine CAMPUS Employee (including SOM employees working at UCIMC)
- Student Employee
- UC Irvine Student Only (Not an employee)
- Other

3. Was a vehicle involved?

- Yes
- No