UCI Environmental Health & Safety

Biosafety Manual

Responsible Administrator: Biosafety Officer
Revised: October 2022

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

1.0 PROGRAM DESCRIPTION

UC Irvine Biosafety Manual specifies the practices, procedures and requirements for the safe handling and use of

biohazardous materials for research and teaching activities at UCI and UCI Medical Center research facilities (e.g. Building 55). This *Manual* does not apply to the UCI Medical Center hospitals or clinics directly covered under the hospitals' license.

It is the policy of the university that all research and teaching involving biohazardous materials will be conducted in a safe manner to protect the academic community as well as the greater community at large. Further, it is university policy that **NO Risk Group 4 Agents** may be used or stored at UCI.

2.0 SCOPE

2.1 GENERAL APPLICABILITY

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. UCIMC School of Medicine clinical locations are not covered by this manual.

2.2 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 (e.g. Building 55). This *Manual* does not apply to the UCI Medical Center hospitals or clinics directly covered under the hospitals' license.

3.0 DEFINITION

Biohazardous materials and organisms include all infectious agents (bacteria, fungi, parasites, prions, rickettsia, viruses, etc.) which can cause disease in humans or cause significant environmental or agricultural impact. In addition, work with human, primate or sheep tissues, fluids, cells or cell culture; recombinant DNA; transgenic plants, insects, or animals; human gene therapy research; releases of recombinant DNA to the environment; and work with animals known to be reservoirs of zoonotic diseases will be partly or wholly covered by the policies and procedures set forth here.

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)

Please visit the IBC program for more information: https://www.ehs.uci.edu/research-safety/biosafety/ibc/index.php

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.

The Principal Investigator is responsible for full compliance with the practices and procedures set forth in this *Manual*. This responsibility extends to all aspects of biosafety involving all individuals who enter or work in the PI's laboratory or collaborate in carrying out the PI's research. Although the PI may choose to delegate aspects of the biosafety program in his/her laboratory to other laboratory personnel or faculty, this does not absolve the PI from the ultimate responsibility. The PI remains accountable for all activities occurring in his/her lab. Documentation of training and compliance with appropriate biosafety practices and procedures is essential.

General Responsibilities

As part of the general responsibilities, the Principal Investigator shall:

- Delay initiation or modification of biohazardous materials work which requires prior Institutional Biosafety Committee (IBC) approval (e.g., recombinant DNA, Select Agent, or where Biosafety Level-3 containment is required) until that work, or the proposed modification, has been approved by the IBC and has met all other requirements of this *Manual* and any protocol specific requirements. Guidelines for research involving recombinant DNA molecules are available at: https://osp.od.nih.gov/biotechnology/nih-guidelines/
- Ensure that any research projects requiring approval prior to the initiation of work by the NIH, or any other agency be reviewed and approved by the IBC prior to obtaining agency approval.
- Notify the IBC prior to the initiation of work requiring the use of biohazardous materials.
- Ensure that all laboratory personnel, maintenance personnel and visitors who may be exposed to any biohazard are informed in advance of their potential risk and of the behavior required to minimize that risk. It is essential that everyone who may have any potential exposure to biohazardous materials enter and/or work in the laboratory under the principle of informed consent.
- Ensure that all maintenance work in, on, or around contaminated equipment is conducted only after that equipment is thoroughly decontaminated by the laboratory staff.
- Report any significant problems, violations of the policies, practices and procedures set forth in this *Manual*, or any significant research related accidents and illnesses to the Biosafety Officer within 24 hours at (949) 824-6200 and ibc@uci.edu.
- Notify the Biosafety Officer immediately if a laboratory-acquired infection is known or suspected.
- Be adequately trained in good microbiological techniques.
- Ensure that all research personnel are appropriately trained in biosafety and receive appropriate medical surveillance when needed. To sign up for EH&S provided training, visit www.uclc.uci.edu.
- Develop (with the assistance of the Biosafety Officer) emergency plans for handling accidental spills and personnel contamination.
- Create and foster an environment in the laboratory which encourages open discussion of biosafety issues, problems, and violations of procedure. The PI will not discipline or take any adverse action against any person for reporting problems or violations to the Biosafety Officer or IBC.
- Comply with shipping requirements for biohazardous materials and infectious agents.

Submissions of Proposed Work to the Institutional Biosafety Committee (IBC)

The Principal Investigator shall:

- Make an initial determination of the required levels of physical and biological containment in

accordance with the requirements set forth in this *Manual*.

- Select appropriate microbiological practices and laboratory techniques to be used for the research.
- Submit any significant changes to the Biosafety Officer and/or the IBC for review and approval. Examples could include: i) a change in Biosafety Level, e.g., work with mouse cells is changed to work with human or primate cells; ii) work begins with a new cell line that carries a potentially infectious organism; work with a small part of an agent's genome is modified to working with>2/3 of that genome; iv) addition or change in animal species; v) change in host-vector system; etc.

Prior to Initiating Research

The Principal Investigator shall:

- Make available to all laboratory staff protocols that describe the potential biohazards and the precautions to be taken.
- Instruct and train all research personnel in: (i) the practices and techniques required to ensure safety and (ii) the procedures for dealing with accidents.
- Inform the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection).
- Ensure that collaborators are made aware in advance of any biohazardous material sent to them and the biosafety precautions to be followed. Principal Investigators are advised to maintain a log of all biological material received and sent out.

During the Conduct of the Research

- The Principal Investigator shall:
- Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed.
- Investigate and report any significant problems pertaining
- Immediately notify the Biosafety Officer of any laboratory spills, accidents, containment failure or violations of biosafety practice which result in the release of biohazardous material and/or the exposure of laboratory personnel (or the public) to infectious agents.
- Correct work errors and conditions that may result in the release of biohazardous materials.
- Ensure the integrity of all containment systems used in the project.
- Restrict access as required by the laboratory-specific biosafety practices procedures and by the biosafety containment level approved by the IBC and the Biosafety Officer.

4.4 UCI BIOSAFETY OFFICER

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

Services to the Laboratories

- Conduct periodic inspections to ensure that required laboratory practices and procedures are rigorously followed.
- Assist Principal Investigators and research staff in developing exposure control plans; 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.

Training Services

- 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.

Institutional Biosafety Committee Support

- 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.

Services on Behalf of the Laboratories

- 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.

The laboratory staff members are the most critical element in maintaining a safe working environment. Each person must look out for their own safety and that of their co-workers. If individuals do not follow the university and laboratory-specific biosafety practices and procedures in the conduct of their laboratory duties, we cannot have a safe working environment. It is the laboratory staff's responsibility to:

- Conscientiously follow lab-specific biosafety practices and procedures.
- Report to the Principal Investigator or the lab supervisor all problems, violations in procedure or spills as soon as they occur.
- Report to the Biosafety Officer 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 Principal Investigator, the Biosafety Officer or the Institutional Biosafety Committee.

5.0 PROGRAM COMPONENTS

5.1 INSTITUTIONAL BIOSFAETY COMMITTEE REVIEW AND 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 using biohazardous materials and infectious agents must complete an online IBC (Institutional Biosafety Committee) form, which can be accessed by visiting the following website: https://www.ehs.uci.edu/research-safety/biosafety/ibc/index.php

LEAD RESEARCHER ELIGIBILITY

All proposals presented from the laboratory of a faculty member who has responsibility for assigned space shall be treated as if they belong to that faculty member. Lead Researchers are eligible to submit applications to the IBC for biological materials in research. In some cases, the Lead Researcher may not be eligible as a Principal Investigator. The type of appointment an individual has with UCI determines whether they may serve as a Lead Researcher on their own or whether a Faculty Sponsor is required. For more information regarding eligibility, visit: https://research.uci.edu/sponsored-projects/pi-eligibility-project-leadership/

INFORMATION SUBMITTED FOR IBC REVIEW

The combination of all work proposed by a laboratory group, regardless of the source of funding (or even lack of funding), shall be subject to a comprehensive "umbrella" review.

For the purposes of this proposal review format, a Principal Investigator shall be regarded as the ultimate, single point of accountability and responsibility for a given laboratory. A Principal Investigator is defined as a faculty member who i) has assigned laboratory space and ii) is ultimately responsible for the work carried out in such space.

The PI must specify:

- Type of research (i.e. infectious agent, rDNA, etc.)
- What procedures are being carried out;

- Where each aspect of the work is being done; and
- Who the researchers, lab workers and collaborators are.

MODIFICATIONS TO APPROVED RESEARCH

The PI must notify the IBC and obtain approval **before** changing any variable which may carry increased biohazard risk. As a working principle, PI's must decide if new

agent or protocol poses any new or increased hazards from those indicated in the currently approved proposal. If there are new or increased hazards (or if there is any doubt or question), approval must be sought prior to implementing the change.
Approval must be sought and obtained from the IBC prior to the initiation of work involving any of the following:

- new viruses, new vector systems (including bacterial and fungal plasmid systems).
- work with non-human systems being changed into work in human systems.
- work with new cell lines not previously approved.
- changes in constructs or systems that result in significantly higher titers.
- enhanced replication or infectivity.
- expression of toxic products.
- partial genomes increased to more than two-thirds of whole genome.
- new or altered procedures that pose increased risk of aerosol or other type of exposure.
- addition of procedures or agents that require a change in Biosafety Level.
- new or the addition of procedures involving biohazardous materials in animals.

COMMITTEE REVIEW AND DECISION

The IBC meets on the second Wednesday of each month to review and discuss the study applications received by the submission date. After a majority vote, the protocols will be placed in one of the following categories:

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.

Letters detailing the IBC's concerns will be sent to the PI within three days after the meeting date.

5.2 BIOSAFETY LEVEL PRACTICES CHART

UCI LAB CONTAINMENT LEVELS FOR BIOLOGICAL RESEARCH INVOLVING POTENTIAL BIOHAZARDS

BIOSAFETY LEVELS (BSL)	BSL1	BSL2	BSL-3 Practice in BSL-2 Facilities (BSL2+)	BSL3
A. HAZARD LEVELS				
Degree of hazard	Low Risk: non-pathogenic E. coli K-12, B strains	Low to Moderate; Herpes viruses, Foodborne Pathogens: Salmonella, Shigella, pathogenic E.coli	Moderate to High: specific experiments w/ BSL3 agents which the IBC authorizes in BSL2 facilities: 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 PRACTICES				
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 EH&S	Pickup by EH&S	Pickup by EH&S	Autoclave, then removal from lab by EH&S
4. Pipetting	Mechanical device	Mechanical device	Mechanical device	Mechanical device

BIOSAFETY LEVELS (BSL)	BSL1	BSL2	BSL-3 Practice in BSL-2 Facilities (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	Required (foot/elbow/electronic operation recommended)	Required (foot/elbow/electronic operation)
7. Aerosol minimization procedures	Required	Required	Required	Required
C. SPECIAL PRACTICES				
1. Autoclave	Not Required for biohazardous BSL1 waste	Not required prior to pick up by EH&S	Maybe required prior to pick up by EH&S	Required, preferably in laboratory then picked up by EH&S
2. Insect/rodent control program	Required	Required	Required	Required
3. Transport of biohazardous waste material for processing (decontamination) away from lab	Red bags in durable, closed, specially marked, leak-proof containers	Red bags in durable, closed, specially marked, leak-proof containers	Red bags in durable, closed, specially marked, leak-proof containers	Red bags in durable, closed, specially marked, leak-proof containers
Note 1: Biohazardous waste must be placed in marked, closed, leak-proof containers and under direct control of the responsible lab worker(s) until it is picked up by EH&S.				

BIOSAFETY LEVELS (BSL)	BSL1	BSL2	BSL-3 Practice in BSL-2 Facilities (BSL2+)	BSL3
D. 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 are used when procedures with a high potential for creating aerosols are being conducted with biohazardous materials. (See note 2 below) If high concentrations/ large volumes of biohazardous materials are used, some types of material may be centrifuged in the open laboratory if sealed heads or centrifuge safety cups are used, and if the containers are opened only in a biological safety cabinet. 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. (See note 3 below) 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. (See note 3 below) Equipment must be decontaminated immediately after use.
3. Freezers/ refrigerators	No biohazard sign required	Biohazard sign must be posted and containers must be labeled	Biohazard sign must be posted and containers must be labeled	Biohazard sign must be posted and containers must be labeled
4. BSC Certification	Recommended certified annually	Certified annually	Certified annually	Certified annually

BIOSAFETY LEVELS (BSL)	BSL1	BSL2	BSL-3 Practice in BSL-2 Facilities (BSL2+)	BSL3
5. HEPA-filtered vacuum lines	Required	Required	Required	Required
6. BSC work surface decontamination	Daily & following spills	Required before and after each use	Required before and after each use	Required before and after each use
7. Personal Protective Equipment (PPE) when working within primary containment (e.g. BSC)	Required – long pants or equivalent and closed-toe shoes, gloves should be worn when handling infected animals and when skin contact with hazardous materials is unavoidable	Required – long pants or equivalent and closed-toed shoes and appropriate combinations of special protective clothing, gloves, etc., are used for all activities with biohazardous materials. (See note 4)	Required - long pants or equivalent and closed-toed shoes appropriate combinations of special protective clothing, gloves, etc., are used for all activities with biohazardous materials. (See note 4)	Required - long pants or equivalent and appropriate combinations of special protective clothing *plus NIOSH N95 respirators or better must be worn in rooms containing infected animals.*
8. Laboratory coats	Recommended (front button coats)	Required (front button coats)	Wrap around disposable clothing required for all workers with potential exposure to biohazardous materials	Required (wrap around disposable clothing)
9. Personal Protective Equipment (PPE) when working outside of primary containment	Required - long pants or equivalent and closed-toe shoes, Gloves should be worn when handling infected animals and when skin contact with biohazardous materials is unavoidable. Safety glasses	Required - appropriate combinations of special protective clothing plus a minimum of NIOSH N95 respirators or better must be worn in rooms containing infected animals *or as directed by the IBC.* Goggles	Required - appropriate combinations of special protective clothing plus NIOSH N95 respirators or better must be worn in rooms containing infected animals. Additional PPE may be required based on IBC review. Goggles	Required - appropriate combinations of special protective clothing plus NIOSH N95 respirators or better must be worn in rooms containing infected animals. Goggles

BIOSAFETY LEVELS (BSL)	BSL1	BSL2	BSL-3 Practice in BSL-2 Facilities (BSL2+)	BSL3
Note 2: These procedures with a high risk of aerosol potential include centrifuging, grinding, blending, vigorous shaking or mixing, sonic disruption, opening containers of biohazardous materials whose internal pressures may be different from ambient pressures, inoculating animals intranasally and harvesting infected tissues from animals or eggs.				
Note 3: These procedures include manipulation of cultures and of clinical or environmental material that may be a source of aerosols containing biohazardous materials; the aerosol challenge of experimental animals; harvesting of tissues from infected animals and embryonic eggs and necropsies of infected animals.				
Note 4: Required with aerosol generating equipment; manipulation of high concentrations or large volumes of biohazardous materials; activity involving all clinical specimens; body fluids and tissues from humans or from infected animals or eggs; human cell culture; necropsies of infected animals.				
E. LABORATORY FACILITIES				
1. Ventilation	Negative pressure; no recirculation of air to other areas of the building	Negative pressure; 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	Required on lab doors in areas where biohazardous materials are stored and where work is done	Required on lab doors in areas where biohazardous materials are stored and where work is done
3. Bench top work	Permitted	Permitted only for procedures with a low-risk of splash, splatter, or aerosol production	Not permitted	Not permitted
4. Operable windows	Permitted with fly screens	Permitted with fly screens	Not permitted	Not permitted

BIOSAFETY LEVELS (BSL)	BSL1	BSL2	BSL-3 Practice in BSL-2 Facilities (BSL2+)	BSL3
5. Laboratory separated from the general public	No	No	Yes. Doors must be closed and locked when work is being done with biohazardous materials	Yes. Doors must be closed and locked at all times.
F. OTHER REQUIREMENTS				
1. Technical Training	Required with documentation	Required with documentation	Required with documentation	Required with documentation
2. Medical Surveillance (baseline serology)	Required when appropriate	Required when appropriate	Required to be offered	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; personnel required to be familiar with policies & procedures.	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.

5.3 INFECTIOUS AGENTS

5.3.1 INFECTIOUS AGENTS AND THE LAB WORKER

A laboratory-acquired infection was defined by Sulkin and Pike (1951) as one that resulted from laboratory work, whether it occurred in a laboratory worker or in another person who happened to be exposed as a result of research or clinical work with infectious agents. **If you are immune-compromised you are at a much higher risk of acquiring infections and you should meet with the EH&S Occupational Health Coordinator for a medical consultation to determine your risk of infection.**

5.3.2 MODES OF INFECTIONS

Microorganisms can enter the body through the mouth, the respiratory tract, broken or intact skin and the conjunctivae. It should be noted that in laboratory-acquired infections, the route may not be the same as when the disease is acquired naturally.

Infectious materials and cultures of microorganisms accumulate in large amounts in clinical and microbiological laboratories and, as it is necessary to transfer them from one container to another and to manipulate them in various ways, the potential hazards are much greater than in most other occupations. Nevertheless, according to UCI EH&S and IBC requirements, documented, deliberate effort must be exerted by Principal Investigators and lab workers to make certain that nobody is exposed to biohazards.

Modes of infection can be classified into two categories:

- **Infections preceded by overt personal accidents, which include:**

  - Inoculation (resulting from pricking, jabbing or cutting the skin with contaminated instruments such as hypodermic needles, scalpels and glassware; and from animal bites or scratches).
  - Ingestion (resulting from mouth-pipetting, eating, drinking and smoking, which is why these practices are not permitted in the lab).
  - Splashing into the face and eyes.
  - Spillage and direct contact.

Infections not preceded by overt personal accidents:

Aerosols, droplets, and fomites are speculated (from Pike's 1976 data) to be responsible for up to 82 percent of all laboratory-acquired infections. Aerosols are defined as a cloud of very small liquid droplets produced whenever energy is applied to a liquid, and such liquid is allowed to escape into the environment. It has been shown (Wells, 1934) that if the liquid contains infectious agents, these would be distributed in the aerosol and would remain viable for some time. The larger droplets (greater than 0.1 mm in diameter) will settle quickly and contaminate the surfaces upon which they come to rest. The smaller droplets do not settle but evaporate very rapidly. It was found that those with diameter of 0.1 mm would evaporate in 1.7 seconds, and those with a diameter of 0.05 mm would evaporate in 0.4 seconds.

The infectious agents in the droplets remain in a dried state as "droplet nuclei" or fomites. The smaller the number of organisms and amount of dried material, the longer they will remain airborne, and are moved around buildings by air currents generated by ventilation and people traffic.

It has been shown that many laboratory techniques using both simple and complex mechanical equipment, as well as laboratory accidents, produce aerosols. These include use of pipettes, syringes and needles, opening tubes and bottles, use of centrifuges and blenders, harvesting of eggs and other virological procedures, lyophilization, and breakage of cultures.

There are many regulations in place to forestall the problem of laboratory-acquired infections. However, the responsibility for compliance with the regulations still lies primarily with the Principal Investigator and, secondarily, with the laboratory staff.

In addition, it is crucial for the PI and laboratory groups to always bear in mind that a large number of organisms that would ordinarily be innocuous can be infective in immunocompromised persons. Therefore, additional, and more stringent measures must be established by the PI in an effort to prevent the occurrence of lab-acquired infections in such individuals.

5.4 WORK WITH INFECTIOUS AGENTS AT UCI

Research or teaching activities involving infectious agents must be conducted with prior approval by the Institutional Biosafety Committee (IBC). Researchers and students must follow requirements as specified in the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories Manual (https://www.cdc.gov/labs/BMBL.html) as the minimum containment required for this work. Containment requirements may be subject to modification by the IBC.

Storage of Infectious Materials

Infectious materials must be clearly identified and stored in such a manner as to preclude accidental exposure. This normally includes double containment and labeling the containment device (e.g., freezer, refrigerator, liquid nitrogen tank).

A number of infectious agents have been documented as causes of laboratory- acquired infections. They include bacterial, viral, chlamydia and rickettsia, and parasitic organisms, as listed below:

5.4.1 PRIONS

Prions are proteinaceous infectious particles that lack nucleic acids. Prions are composed largely, if not entirely, of an abnormal isoform of a normal cellular protein.

- **Prion Diseases**

Disease	Natural Host	Prion
Scrapie	sheep and goats	scrapie prion
Transmissible mink encephalopathy (TME)	mink	TME prion
Chronic wasting disease (CWD)	mule deer and elk	CWD prion
Bovine spongiform encephalopathy (BSE)	cattle	BSE prion
Feline spongiform encephalopathy (FSE)	cats	FSE prion
Exotic ungulate encephalopathy (EUE)	nyala and greater kudu	EUE prion

Kuru	humans	kuru prion
Creutzfeldt-Jakob disease (CJD)	humans	CJD prion
Gerstmann-Sträussler-Scheinker syndrome (GSS)	humans	GSS prion
Gatal familial insomnia (FFI)	humans	FFI prion

5.4.2PSDS FOR INFECTIOUS AGENTS

Pathogen Safety Data Sheets (PSDSs), previously titled Material Safety Data Sheets for infectious substances, are technical documents that describe the hazardous properties of a human pathogen and recommendations for work involving these agents in a laboratory setting. These documents have been produced by the Public Health Agency of Canada as educational and informational resources for laboratory personnel working with these infectious substances. To access the PSDSs, visit: https://www.canada.ca/en/public-health/services/laboratory-biosafety- biosecurity/pathogen-safety-data-sheets-risk-assessment.html

5.4.3RECOMBINANT DNA, GENE THERAPY AND TRANSGENICS

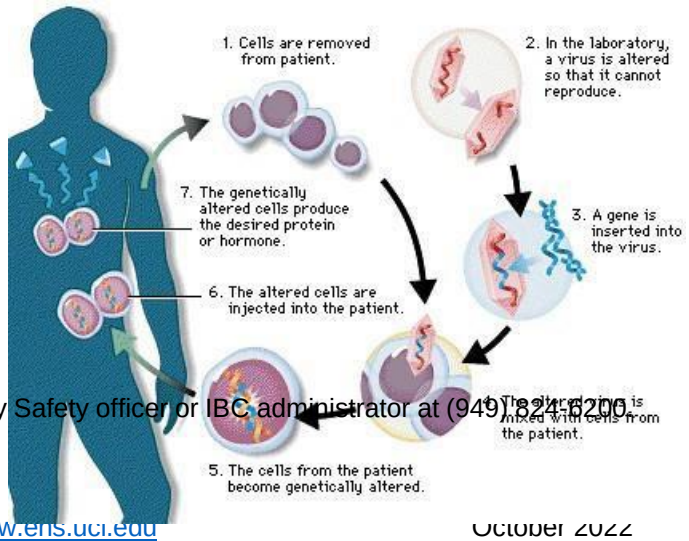
- **RECOMBINANT DNA**

Experiments involving the generation of recombinant DNA (rDNA) normally require registration and approval by the IBC. The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)[1] is the definitive reference for rDNA research in the United States and has been adopted by UCI. If the experimental protocol is not covered by the guidelines, contact the UCI Biosafety Officer at (949) 824-6200 for determination of further review. UCI labs using recombinant DNA must submit a form for IBC approval http://www.ehs.uci.edu/programs/biosafety/ibc/index.html.

If you have any specific questions about a particular host-vector system not covered by the guidelines, please call the Biosafety Officer to request review by the IBC. Guidelines are published in the **Federal Register**.

- **HUMAN GENE THERAPY**

All proposed clinical trials involving rDNA for human gene therapy requires registration and approval from both campus (Institutional Biosafety Committee, Institutional Review Board, etc.) and federal (NIH, FDA, etc.) agencies prior to initiation of experiments. The



IBC requirements for human gene therapy protocols are detailed in Section III-C of the NIH Guidelines for Research Involving Recombinant DNA Molecules. For more details about IBC approval of human gene therapy protocols, call the Biosafety Safety officer or IBC administrator at (949) 824-6200.

5.4.4 TRANSGENICS

A transgenic organism is an organism whose genome has been altered by the transfer of a gene or genes from another species or breed.

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[1] As of May 2020, the most current version is April 2019

Transgenic Animals

Investigators who create transgenic animals must complete in IBC form and submit it to EH&S for IBC approval prior to initiation of experimentation. The breeding of two different strains of transgenic rodents potentially generates a new strain of transgenic animals and may be an activity that is covered under the NIH guidelines requiring IBC review and approval. The creation of transgenic rodents falls under one or two portions of the NIH guidelines depending on the containment level required to house the rodents. In addition, the Institutional Animal Care and Use Committee (IACUC) require that these protocols be approved by the IBC prior to full approval by the IACUC. Animal research that involves the use of hazardous agents (chemical, radiological, or biological) must have a safety consideration meeting as part of the Safety In Research and Vivarium Environments (SIRVE) program.

Transgenic Animal Disposal Guidelines

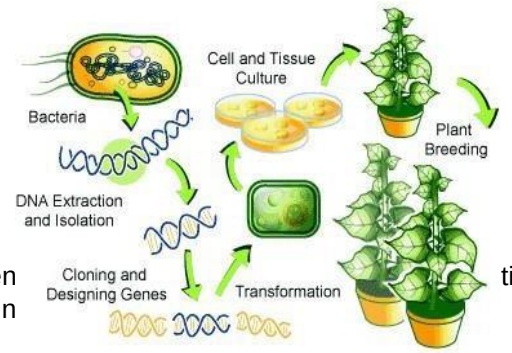
The National Institutes of Health (NIH) has established strict guidelines on the proper use and disposal of transgenic animals, plants, and other forms of recombinant DNA (rDNA) in research. The NIH Guidelines outlines institutional and investigator responsibilities. For more information on the UCI Transgenic Animal Disposal Guidelines, visit http://www.ehs.uci.edu/programs/biosafety/ibc/TransgenicProgram.doc.

When a transgenic animal is euthanized or dies, the carcass must be disposed of by incineration (pathology waste) or other method approved by the IBC and EH&S. This applies to confirmed transgenic animals, potentially transgenic animals, “no-takes” in the production of transgenic animals, and progeny of transgenic animals. No changes to the approved disposal protocol are allowed without prior review and written approval.

Pathology waste guidelines can be found at: http://www.ehs.uci.edu/programs/enviro/Pathology.pdf.

Transgenic or Exotic Plants or Pests

Experiments to genetically engineer plants by recombinant DNA methods may require registration with the IBC. To prevent release of transgenic plant materials to the environment, the NIH rDNA guidelines provide specific plant biosafety containment recommendations for experiments involving the creation and/or use of genetically en



tic plants or pests may necessitate additional training, contain

The Biotechnology Regulatory Services (BRS) of the United States Department of Agriculture Animal and Plant Health Inspection Service (USDA-APHIS) implements regulations for certain genetically engineered (GE) organisms that may pose a risk to plant health. Please visit the APHIS website for more information about BRS: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology

Contact the Biosafety Officer at (949) 824-6200 for additional information.

6.0 BLOODBORNE PATHOGENS, UNIVERSAL PRECAUTIONS, HUMAN TISSUE AND CELL CULTURE

6.1.1 DEFINITIONS

Bloodborne pathogens (BBP) are pathogenic microorganisms that are present in human "blood" and "other potentially infectious material." These pathogens include hepatitis B virus (HBV), hepatitis C (HCV), human immunodeficiency virus (HIV), syphilis, malaria and many others.

"Blood" means human blood, human blood components and products made from human blood.

"Other Potentially Infectious Materials" means:

- The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any other body fluid that is visibly contaminated with blood and all undifferentiated body fluids in emergency response situations.
- Any unfixed tissue or organ (other than intact skin) from a human.
- Human cells, HIV-containing cell or tissue cultures, organ cultures and HIV, HBV, or HCV-containing culture medium or other solutions; and blood, organs or other tissues from experimental animals infected with HIV, HBV, or HCV.
- Note: An individual is also considered occupationally exposed if they use equipment that is used to process or store blood, other potentially infectious materials or bloodborne pathogens, even if they do not have direct contact with blood or other potentially infectious material.

"Universal Precautions" is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids/tissues/cell lines are treated as if known to be infectious for HIV, HBV, HCV and other bloodborne pathogens.
http://www.cdc.gov//niosh/topics/bbp/universal.html

6.1.2 BLOODBORNE PATHOGENS EXPOSURE CONTROL PLAN

The Occupational Safety Health Administration (OSHA) regulates facilities where employees could be exposed to bloodborne pathogens by promoting safe work practices to minimize the incidence of disease caused by these pathogens. California OSHA (Cal OSHA) enacted the BBP standard (8 CCR §5193). The purpose of the standard is to reduce occupational exposure to human bloodborne pathogens that employees may come in contact within the workplace, and to establish a framework for training and medical response.

UCI's Exposure Control Plan (ECP) was developed to comply with the standard. The ECP provides guidelines and procedures to prevent or minimize occupational exposure to BBP's. The ECP is a policy of the University in concert with the IBC; both provide mandatory training for employees with a reasonable anticipated exposure to human blood, body fluids, and other potentially infectious materials as a result of performing their job duties.

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

A. Implement a written Exposure Control Plan which adopts BSL2 or higher containment practices and procedures.

B. Perform and document the following:

1. Exposure determination
2. Procedure for the evaluation of exposure incidents

3. Hepatitis B vaccination and follow up
4. Training
5. Record keeping

6.1.3 METHODS OF COMPLIANCE

Universal Precautions

UCI observes the concept of Universal Precautions which is an approach to infection control whereby all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, HCV and other BBP's. Follow BSL2 practices and procedures for all teaching, clinical, research or other work with human blood, tissues, cells, and fluids.

All laboratory coats and contaminated items should be decontaminated (i.e., steam autoclaved, chemical disinfection) prior to cleaning and laundry.

Engineering & Work Practice Controls

The term "Engineering Controls" refers to controls (e.g., sharps disposal containers, needle-less systems and self-sheathing needles) that isolate or remove the hazard of bloodborne pathogens from the workplace and, therefore, reduce the potential for employee exposure. Other devices include biosafety cabinets and uni-directional airflow from areas of lower to areas of higher hazards.

Work practice controls include frequent handwashing; proper handling and disposal of contaminated needles; no eating, drinking, smoking, application of cosmetics or contact lenses in the lab; and no mouth pipetting.

Food and drink must neither be stored in the same refrigerator, nor on the same shelves, countertops, or benchtops where BBP's are placed. Containers used for storage, transport or shipping of blood-borne pathogens must be labeled properly
(see Shipping Chapter 21 for more information).

Engineered Sharps Injury Protection

Sharps with engineering controls must be used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids. Engineered sharps effectively reduce the risk of an exposure incident by a mechanism such as barrier creation, blunting, encapsulation, withdrawal or other effective mechanisms or a physical attribute built into any other type of needle device, or into a non-needle sharp.

For more information:

http://www.cdc.gov/niosh/topics/bbp/safer/
https://www.osha.gov/needlesticks/needlefaq.html

For a list of sharps vendors, visit:
http://blink.ucsd.edu/safety/research-lab/biosafety/bloodborne/sharps/vendors.html

Personal Protective Equipment (PPE)

In addition to engineering controls, personal protective equipment must also be used. For research involving potential exposure to BBP the minimum required PPE includes long pants or equivalent, closed-toe shoes, gloves, lab coats, eye protection or face shields. Additional PPE such as gowns and masks may be used as appropriate.

Housekeeping

A generally clean and sanitary laboratory environment must be maintained. There must be a regular and proper decontamination of all work surfaces, equipment, bins, cans and other similar receptacles intended for reuse. Regulated waste must be separated into contaminated sharps and other wastes, then stored and disposed of in proper containers.

HBV VACCINATION & POST-EXPOSURE

For more information regarding vaccinations and post-exposure evaluation, visit the Occupational Health Program at: https://ehs.uci.edu/research-safety/occupational-health/occupational-health-services.php

General

The University (by means of funding provided by the department or PI or EH&S) must make the hepatitis B 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.

Hepatitis B Vaccination

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. Those who decline the Hep B vaccine must sign a Letter of Declination that is available inside the online Bloodborne Pathogens course via the UCLC (https://www.uclc.uci.edu/). The original signed letter should be kept in the employee's file. 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 & Follow Up

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.

***Testing of a person's blood must conform to current California state laws and guidelines.**

Information to Health Care Provider

For an employee who is simply being vaccinated, the responsible health care professional must be provided a copy of the BBP Standard. For an employee who is being followed up after an exposure incident, the responsible health care professional must be provided with the BBP Standard, a description of the exposed employee's duties, documentation of circumstances and route(s) of exposure, results of source individual's blood testing and all pertinent medical records.

Health Care Provider's Written Opinion

Written opinion for routine vaccination must be limited to whether the hepatitis B vaccination is indicated and whether the employee has received it. Written opinion for post-exposure evaluation and follow up, on the other hand, must be limited (for the purposes of patient confidentiality) to the following information:

- That the employee has been informed of the results of the evaluation; and
- That the employee has been told about medical consequences of exposure which might require further evaluation or treatment.

6.1.4 HAZARD COMMUNICATION

Labels and Signs

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

Labeled red bags and labeled containers are used for biohazardous waste and sharps 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).

Information and Training

Training must be conducted during working hours and at no cost to the employee. The training must be conducted at the time of initial assignment of employee and annually thereafter, where annually means within one year of previous training.

The training material must be tailored to match the educational level of the employees.

Elements of the training include:

- Access to copies of the Bloodborne Pathogen Standard
- Epidemiology and clinical features of Bloodborne diseases
- Explanation of Exposure Control Plan
- How to recognize tasks that carry risk of occupational exposure
- Explanation of engineering controls, work practices and personal protective equipment
- Basis for Personal Protective Equipment selection
- Information on and explanation of emergency procedures
- Information on signs, labels and color-coding
- Opportunity for interactive questions and answers session with the trainer

6.1.5 RECORDKEEPING

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.

Training Records

Training records must be established and maintained. These records should include date of training; contents or summary of training; names, qualifications and signature of trainer(s); names, job titles and signatures of trainees; and a signed statement by trainees that they understand and agree to conduct their work in accordance with the training precepts. This record must be maintained for a minimum of three years from the date of training.

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.

5.7.7 WORKING WITH HUMAN TISSUES

All human blood, blood products, body fluids and tissues are listed as potentially infectious materials. Established human cell lines must be treated as if they are potentially infected with Bloodborne Pathogens and laboratories working with these materials must have annual Bloodborne Pathogens training.

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.

Biosafety Level 2 practices and procedures must be followed when handling human blood, blood products, body fluids and tissues because of the infectious agents they may contain, including established human cell lines.

Biosafety Level 2 practices and procedures are consistent with the concept known as "Universal Precautions" which requires all specimens of human blood, blood products, body fluids and tissues to be treated as if they are infectious. In 1991, Cal/OSHA promulgated a standard to eliminate or minimize occupational exposure to hepatitis B Virus (HBV), hepatitis C Virus (HCV), human immunodeficiency virus (HIV) and other bloodborne pathogens. This regulation embraces the federal regulation, **Occupational Exposure to Bloodborne Pathogens**, and mandates a combination of engineering and work practice controls, training, and hepatitis B vaccination. Other provisions are included to help control the health risk to employees resulting from occupational exposure to human blood and other potentially infectious materials which may contain these or other specified agents.

Hepatitis B vaccination is available at no cost to all occupationally at-risk university employees. Please refer to the EHS website for information on obtaining the hepatitis B vaccine or titer. Mandatory safety training, which provides information on protection from occupational exposure to Bloodborne pathogens, is provided by EH&S to each laboratory on an annual basis. For more information on training, call EH&S at (949) 824-6200 or visit the UC Learning center at www.uclc.uci.edu to register for online bloodborne pathogens training.

Investigators using human blood, blood products, body fluids or tissues must complete a laboratory-specific Exposure Control Plan. The completed plan must be readily available in the laboratory for all workers.

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

A. The employee must attend annual Bloodborne pathogens biosafety training offered by EH&S.

B. The employee must have prior experience in the handling of human pathogens or tissue cultures before working with HIV, HCV or HBV.

C. 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.

D. 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 Principal Investigator/laboratory supervisor.

5.8.8 Cell Culture

When cell cultures are known to contain an etiologic agent, an oncogenic virus or amphotropic packaging system the cell line must be classified at the same level as that recommended for the agent.

Furthermore, the following must be handled at BSL2 or higher containment level:

- All cell lines of human/primate origin, including established cell lines
- Any cell lines derived from lymphoid or tumor tissue
- All cell lines exposed to or transformed by any oncogenic virus
- All cell lines exposed to or transformed by amphotropic packaging systems
- All clinical material (e.g., samples of human tissues and fluids obtained after surgical resection or autopsy)
- All cell lines new to the laboratory (until proven to be free of all adventitious agents)
- All mycoplasma-containing cell lines

UCI IBC Guidance on the Safe Handling of Human Cell Lines

https://www.ehs.uci.edu/programs/biosafety/UCI_Cell_Line_Guidance.pdf

UNIVERSAL PRECAUTIONS

Universal precautions is an approach to infection control whereby all human/primate blood and other human/primate body fluids, tissues and cells are treated as if known to be infectious for HIV, HBV, HCV and other bloodborne pathogens (BBP's).

Aspects of Universal Precautions include frequent handwashing; proper handling and disposal of contaminated needles; no eating, drinking, smoking or application of cosmetics or contact lenses in the lab; and no mouth pipetting. Food and drink must not be stored in the same refrigerator, nor on the same shelves, countertops, or benchtops where BBP's are placed. Eating and drinking is allowed only in designated "Clean Areas" within BSL1 and BSL2 laboratories. “Clean Areas” are not allowed in BSL3, ABSL3, or Select Agent Labs.

The container for storage, transport, or shipping of BBPs must be labeled properly.

Engineering controls (biosafety cabinets, ventilation, closed top centrifuge rotors, etc.) are the primary methods to control exposures. Personal Protective Equipment (PPE) should also be used to protect personnel from exposures. Personal Protective

Equipment (e.g., gloves, lab coats, gowns, face shields, masks) should be selected and used as appropriate.

All work with human blood, tissues, cells, and other body fluids must be registered with the IBC and conducted using BSL2 containment practices, procedures, and facilities.

6.2 AEROSOL TRANSMISSIBLE DISEASES AND PATHOGENS

6.2.1 DEFINITIONS

Aerosol transmissible diseases (ATD) or aerosol transmissible pathogens (ATP) are diseases or pathogens for which droplet or airborne precautions are required. These agents are listed in Appendix A of the Cal/OSHA ATD Standard (https://www.dir.ca.gov/title8/5199a.html)

Aerosol transmissible pathogen -- laboratory (ATP-L) are pathogens that meet one of the following criteria: (1) the pathogen appears on the list in Appendix D of the ATD standard (http://www.dir.ca.gov/title8/5199d.html), (2) the Biosafety in Microbiological and Biomedical Laboratories (BMBL) recommends biosafety level 3 or above for the pathogen, (3) the biological safety officer recommends biosafety level 3 or above for the pathogen, or (4) the pathogen is a novel or unknown pathogen.

High hazard procedures are procedures performed on a person who is a case or suspected case of an aerosol transmissible disease or on a specimen suspected of containing an ATP-L, in which the potential for being exposed to aerosol transmissible pathogens is increased due to the reasonably anticipated generation of aerosolized pathogens. Such procedures include, but are not limited to, sputum induction, bronchoscopy, aerosolized administration of pentamidine or other medications, and pulmonary function testing. High Hazard Procedures also include, but are not limited to, autopsy, clinical, surgical and laboratory procedures that may aerosolize pathogens (i.e. centrifugation, mixing, vortexing, sonicating, blending, and other aerosol generating procedures).

Zoonotic aerosol transmissible pathogen (Zoonotic ATP) is a disease agent that is 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. Any subsequent references to ATPs shall include Zoonotic ATPs.

If there is any possibility an employee may be exposed to ATPs or ATPs-L during the course of their work, the Principal Investigator must do the following:

A. Implement a written Exposure Control Plan which adopts BSL2 or higher containment practices and procedures.

B. Perform and document the following:

   a. Training
   b. Medical services (including the unavailability of vaccines and respiratory protection)
   c. Exposure incidents
   d. Inspections
   e. Evaluation of engineering controls and other control measures

6.2.2 METHODS OF COMPLIANCE

Verification of Pathogenicity

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.

Engineering & Work Practice Controls

The term "Engineering Controls" refers to controls (e.g. biosafety cabinets, sealed centrifuge rotors or safety cups) that isolate or remove the hazard of aerosol transmissible pathogens 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.

Work practice controls include frequent handwashing; proper handling and disposal of contaminated items; no eating, drinking, smoking, application of cosmetics or contact lenses in the lab; no sniffing of in vitro cultures; and no mouth pipetting.

Food and drink must neither be stored in the same refrigerator, nor on the same shelves, countertops, or benchtops where ATPs or ATPs-L are placed. Containers used for storage, transport or shipping of aerosol transmissible pathogens must be labeled properly **(see Shipping Chapter 21 for more information)**.

Personal Protective Equipment (PPE)

In addition to engineering controls, personal protective equipment must also be used. For research involving potential exposure to aerosol transmissible pathogens, the minimum required PPE includes long pants or equivalent, closed-toe shoes, gloves, lab coats, and eye protection or face shields when splashing is anticipated.

Additional PPE such as respirators (N95 or above) shall be determined based on a risk assessment performed by the PI and Institutional Biosafety Committee (IBC). If respiratory protection is needed, the respirator user must participate in the Respiratory Protection Program. This program requires individuals wearing respirators be medically evaluated, fit-tested and trained to wear the respirator. Training and fit-testing are required at least annually. Individuals will be fit-tested with a minimum protection of an N95 respirator.

Housekeeping

A generally clean and sanitary laboratory environment must be maintained. There must be a regular and proper decontamination of all work surfaces, equipment, bins, cans and other similar receptacles intended for reuse. Regulated waste must be separated into contaminated sharps and other wastes, then stored and disposed of in proper containers.

6.2.3 MEDICAL SURVEILLANCE, VACCINATION & POST-EXPOSURE

For more information regarding medical surveillance, vaccinations and post-exposure evaluation, visit the Occupational Health Program at: https://ehs.uci.edu/research-safety/occupational-health/occupational-health-services.php

The University (by means of funding provided by the department or PI, or EH&S) must make any available ATP 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.

Vaccination

Principal Investigators or Non-Laboratory Supervisors are responsible for ensuring that all employees with potential occupational exposure to ATPs and/or ATPs-L are offered the applicable vaccinations (at no charge to them). Vaccinations shall be made available to all employees with occupational exposures unless the employee has already received the vaccine or it is determined the employee has immunity, or the vaccine is contraindicated for medical reasons. Supervisors (or their designate) must inform all new employees of the vaccination program within 10 working days of their employment start date. If an employee declines to be vaccinated, the Supervisor must ensure that the employee signs the Vaccination Declination Statement provided in the Exposure Control Plan Template and that a copy is on file in the department and EH&S records. If the vaccine is unavailable, supervisors (or their designate) must document efforts made to obtain vaccine and inform employees of vaccine availability status. Vaccine availability must be checked at least every 60 calendar days and employees will be notified when the vaccine is available. Should an employee (still covered under the Standard) who had previously declined decide at a later date to receive the vaccination, it must be made available to him or her at no cost.

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.

Post-Exposure Evaluation & Follow Up

Any exposure (e.g. inhalation of ATPs or ATPs-L) resulting in direct, unprotected contact with ATPs or ATPs-L gives the right to prompt medical evaluation and treatment with a qualified physician familiar with evaluations and treatment protocols as recommended by the Centers for Disease Control and Prevention. These services will be provided at no cost.

After any direct exposure to ATPs-L through a needlestick, immediately wash the affected area with soap and water and NOTIFY YOUR SUPERVISOR. For splashes with ATPs-L, remove contaminated clothing and dispose as biohazard waste, and rinse the affected area for 15 minutes. If necessary, seek medical attention. If ATP or ATPs-L inhalation has occurred, immediately seek medical attention.

The PI/Non Laboratory Supervisor will notify all employees who had significant exposures of the

date, time and nature of the incident within 96 hours of becoming aware of the potential exposure (or sooner if the disease has time restraints for administration of vaccine or prophylaxis, like varicella or meningococcal disease). Employees will be provided post-exposure medical evaluation at no cost to the employee as soon as feasible.

6.2.4 HAZARD COMMUNICATION

Labels and Signs

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).

Information and Training

Training must be conducted during working hours and at no cost to the employee. The training must be conducted at the time of initial assignment of employee and at least annually thereafter, where annually means within one year of the previous training. This training is in addition to the laboratory and agent specific training.

The training material must be tailored to match the educational level of the employees.

6.2.5 RECORDKEEPING

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.

Training Records

Training records must be established and maintained. These records should include date of training; contents or summary of training; names, qualifications and signature of trainer(s); names, job titles and signatures of trainees; and a signed statement by trainees that they understand and agree to conduct their work in accordance with the training precepts. This record must be maintained for a minimum of three years from the date of training.

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.

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 EH&S at (949) 824-6200.

6.2.6 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.

For more information regarding the Laboratory Animal Occupational Health Program, please visit:

https://research.uci.edu/animal-care-and-use/training/laboratory-animal-occupational-health-program/

6.2.7 DISPOSAL OF ANIMALS USED WITH INFECTIOUS AGENTS (CAMPUS OR UCIMC)

Animals must be disposed of through EH&S:
https://ehs.uci.edu/enviro/haz-waste/

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

6.2.8 TRANSGENIC ANIMALS

When a transgenic animal is euthanized or dies, the carcass must be disposed of by incineration (pathology waste) or other method approved by the IBC and EH&S. This applies to confirmed transgenic animals, potentially transgenic animals, "no-takes" in the production of transgenic animals, and progeny of transgenic animals. No changes to the approved disposal protocol are allowed without prior review and written approval.

Pathology waste guidelines can be found at:
https://ehs.uci.edu/enviro/haz-waste/

For additional information regarding the use and disposal of Transgenic Animals, please contact biosafety@uci.edu

6.2.9 ANIMAL ROOM SAFETY INFORMATION

Completion and posting of the Animal Room Safety Information is required for all animal protocols involving use of hazardous materials (See next page for sample biohazard cage card).

ANIMAL ROOM HAZARD COMMUNICATION

Lead Researcher is responsible for:

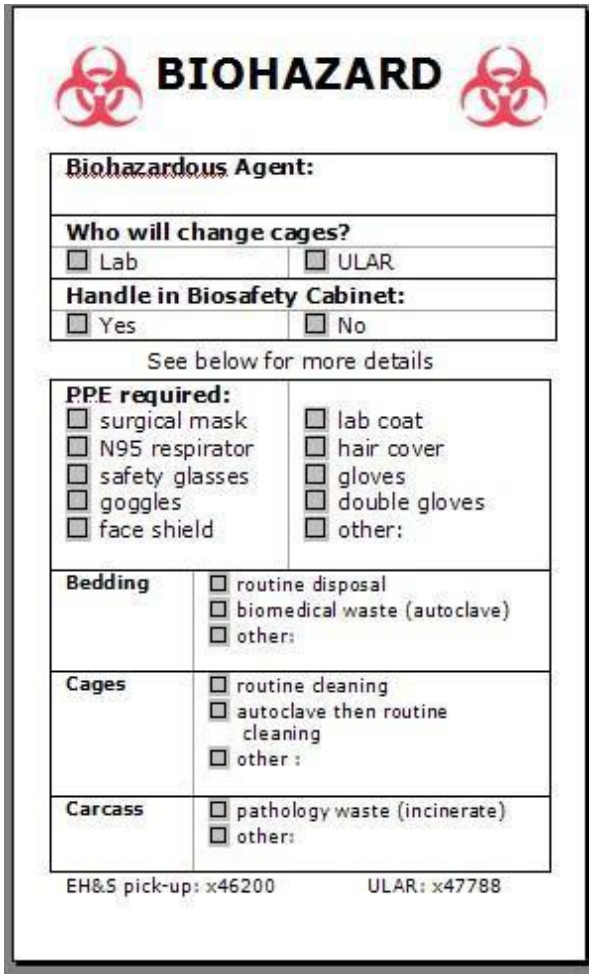
- placing this notice in the Hazard Communication folder at door of animal room when hazards are present;
- labeling the cages with the appropriate hazardous agent cards;
- ensuring that an MSDS is available upon request.

Create a separate hazard communication form for each hazardous agent listed in this IACUC protocol.

Date: *(Expires 3 years from this date)*		**IACUC protocol #:**	
LR Name	**Phone #**	**Emergency Phone #**	**Email**
Lab Contact	**Phone #**	**Emergency Phone #**	**email**
HAZARDOUS AGENT INFORMATION:			
Agent Name: **Hazard Type** *(select one):* Other *(describe):*			

Risk Category *(select all that apply):* Other/Comments*:*	
Routes of Exposure *(click on box for drop-down list, select all that apply):* Other/Comments*:*	
RECOMMENDED VACCINATION *(if handling infected animals or infectious agents):*	
☐ Hepatitis B Vaccine	☐ Other Vaccine *(list):*
PPE FOR ROOM ENTRY *(select all that apply):*	
Other *(describe):*	
PPE FOR ANIMAL HUSBANDRY e.g. cage change *(in addition to PPE listed above):*	
Other *(describe):*	
PPE FOR ANIMAL RESEARCH PROCEDURES IN VIVARIUM *(in addition to PPE listed above):*	
Other *(describe):*	
HAZARDOUS PERIOD *(select one):*	
Other/Comments:	
ENGINEERING CONTROLS DURING HAZARDOUS PERIOD *(select all that apply):*	
Other/Comments*:*	
BEDDING and CAGES *(select all that apply):*	
Other/Comments*:*	

Biohazardous Animal Cage Card



BIOHAZARD

Biohazardous Agent:	
Who will change cages?	
☐ Lab	☐ ULAR
Handle in Biosafety Cabinet:	
☐ Yes	☐ No

See below for more details

PPE required:	
☐ surgical mask	☐ lab coat
☐ N95 respirator	☐ hair cover
☐ safety glasses	☐ gloves
☐ goggles	☐ double gloves
☐ face shield	☐ other:

Bedding	☐ routine disposal ☐ biomedical waste (autoclave) ☐ other:
Cages	☐ routine cleaning ☐ autoclave then routine cleaning ☐ other :
Carcass	☐ pathology waste (incinerate) ☐ other:

EH&S pick-up: x46200 ULAR: x47788

6.3 PERSONAL PROTECTIVE EQUIPMENT

Personal Protective Equipment (PPE) is used to protect personnel from contact with biohazardous materials. Appropriate PPE may also protect the experiment from contamination. PPE must be provided without cost to personnel. The following types of PPE are recommended for regular use.

6.3.1 LABORATORY

Face Protection

Goggles or safety glasses with solid side shields in combination with masks or chin- length face shields, or other splatter guards, are required for anticipated splashes, sprays, or splatters of biohazardous materials. EH&S recommends the use of safety glasses at all times in the laboratory. Information on the availability of low-cost prescription safety eyewear may be obtained by calling EH&S at (949) 824-6200.
Application or removal of contact lenses is not permitted in the laboratory setting where hazards may be present.



Clothing

Laboratory clothing includes: laboratory coats, smocks, scrub suits and gowns. Long- sleeved garments should be used to minimize the contamination of skin or street clothes. In circumstances where it is anticipated that splashes may occur, the garment must be resistant to liquid penetration to protect clothing from contamination. If the garment is not disposable, it must be capable of withstanding sterilization in the event it becomes contaminated. Additional criteria for selecting clothing are: comfort, appearance, closure types and location, antistatic properties and durability.
Protective clothing must be removed and left in the laboratory before leaving for non- laboratory areas. Disposable clothing should be available for visitors and maintenance and service workers in the event they are required. All protective clothing should be either discarded in the laboratory or laundered by the facility.
Personnel must not launder laboratory clothing at home.

Gloves

Gloves must be selected based on the hazards involved and the activity to be conducted. Gloves must be worn when working with biohazardous materials, toxics and other physically hazardous agents. Temperature resistant gloves must be worn when handling hot materials (i.e. working with autoclaves), or extremely cold materials such as liquid nitrogen or dry ice. Delicate work requiring a high degree of precision dictates the use of thin walled gloves. Protection from contact with toxic or corrosive chemicals may also be required. For assistance in glove selection, call EH&S at (949) 824-6200.

When working with hazardous materials, the lower sleeve and the cuff of the laboratory garment should be overlapped by the glove. A long-sleeved glove or disposable arm- shield may be worn for further protection of the garment.

In some instances, double gloving may be appropriate. If a spill occurs, hands will be protected after the contaminated outer gloves are removed. Gloves must be disposed of when contaminated or compromised, removed when work with biohazardous materials is completed and not worn outside the laboratory. Disposable gloves must not be washed or reused.

Respirators

In certain instances, additional respiratory protection may be required. Respirator selection is based on the hazard and the protection factor required. Respirators, including N-95 filtering facepieces must be carefully fitted to the individual and fit tested before confidence can be had in the respirator providing protection. Personnel who require respiratory protection must contact EH&S for assistance in selection of equipment, training in proper usage and enrollment in the UCI Respiratory Protection Program.

Contact EH&S for assistance in selection of other personal protective equipment at (949) 824-6200.

WHICH MASK OR RESPIRATOR SHOULD I USE?

SURGICAL MASK

Appropriate for use:

- To protect animals from humans
- To protect a patient from droplets from personnel
- For use during surgery

Inappropriate for use:

- To protect personnel from infectious or hazardous agents

N95 or N100 RESPIRATOR: Must be cleared by EH&S*

Appropriate for use:

- To protect personnel from most infectious agents
- To protect personnel from animal allergens

Inappropriate for use with:

- Hazardous Chemicals
- Volatile organics such as formaldehyde or carcinogens

CARTRIDGE RESPIRATOR: Must be cleared by EH&S*

Appropriate for use:

- To protect against chemical exposures
- Volatile organics such as formaldehyde or carcinogens
- To protect personnel from most infectious agents
- Will be provided if necessary, after a risk assessment from EH&S

*For N-95 or cartridge respirator use, personnel must have clearance for respiratory protection including:

- Medical Evaluation Form
- Fit testing
- Training

If you have questions regarding the following please contact (949) 824-6200:

- Allergens or Medical Health History
- Infectious agents
- Respiratory Protection

6.4 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
- Ventilation (including air supply, exhaust, and distribution)
- Plumbing
- Emergency Equipment

ACCESS

Corridors, stairways, and exits are important to all persons in the building. Of special interest in the biohazard laboratory is control of access to the laboratory; doors must be kept closed while all BSL2 or greater work is in progress. Be aware of any suspicious activity and report these incidents to the UCI Police Department at (949) 824-5223.

VENTILATION

All UCI laboratories are constructed with single-pass air (100% exhaust through the roof to the outside) and sufficient air volume to exchange the air. Laboratories are also designed to be negatively pressured with respect to areas of lower hazard, such as corridors and offices.

It is the policy of the IBC that all work which requires BSL2 or higher containment be conducted in laboratories which are negatively pressured with respect to their surroundings. As a rule, this includes work involving human or primate tissue culture.

PLUMBING

- About one liter of water should be poured down each of the drains regularly (once per month) to ensure that the traps do not dry out.
- Vacuum systems must be fitted with HEPA filters to prevent biohazardous materials from being sucked into the system.
- Industrial water is normally used in laboratories. If, however, domestic water is plumbed into a laboratory, a valve that prevents backflow must be installed on each line that feeds into the sinks. This is essential to protect others on campus, as well as the community at large.

- Where a hose is attached to the faucet, it must not extend below the top of the sink.

EMERGENCY EQUIPMENT

Fire alarms and detection systems, fire sprinkler systems, eyewashes, douse showers and emergency shut-offs are all installed to make UCI buildings a safer place to work. Each person should familiarize themselves with the location and use of the emergency equipment provided in their building. Since these resources are subject to communal use, all the PI's and lab workers who share the building carry equal responsibility for their proper use and operation.

EH&S must be consulted by any UCI department that is considering implementation of a new design and construction, or considering modifications to an existing design and construction.

5.12 LABORATORY EQUIPMENT

5.12.1 BIOSAFETY CABINETS

Definition/Function

Various laboratory procedures generate aerosols that may spread biohazardous material in the work area and pose a risk of infection to the worker. Biological safety cabinets (BSC) are used to prevent the escape of aerosols or droplets and to protect the research product from airborne contamination.

These devices are distinct from chemical fume hoods and horizontal or vertical laminar flow "clean benches," which should never be used for handling biohazardous, toxic or sensitizing material.

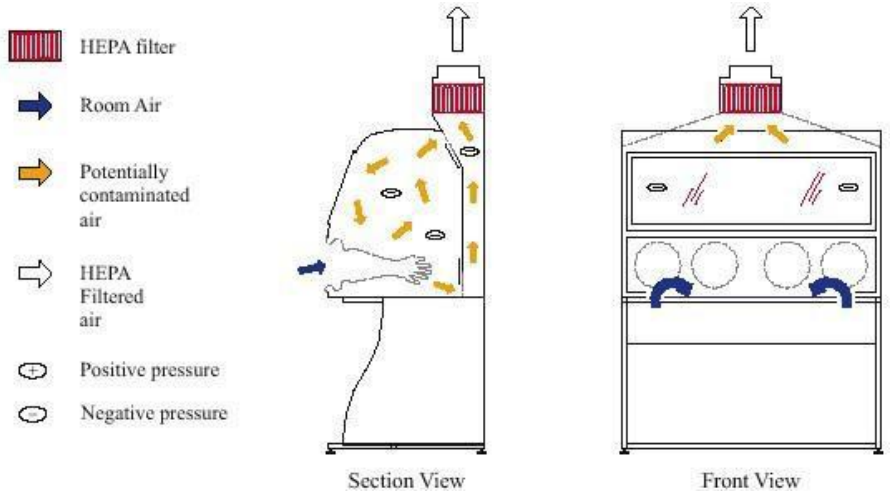
Please refer to: http://www.cdc.gov/biosafety/publications/bmbl5/ (Appendix A)

Types of Biosafety Cabinets

There are three major classes of biosafety cabinets:

- Class I
- Class II
- Class III

Class I biological safety cabinets are enclosures similar to chemical fume hoods, with an inward airflow through the front opening. The exhaust air from the biological safety cabinet is passed through a HEPA filter so that the equipment provides protection for the worker and the public. The product (research material) in the cabinet, however, is subject to contamination. **The IBC discourages the use of Class I biosafety cabinets at UCI. Talk to the UCI Biosafety Officer prior to using a Class I BSC to obtain approval.**



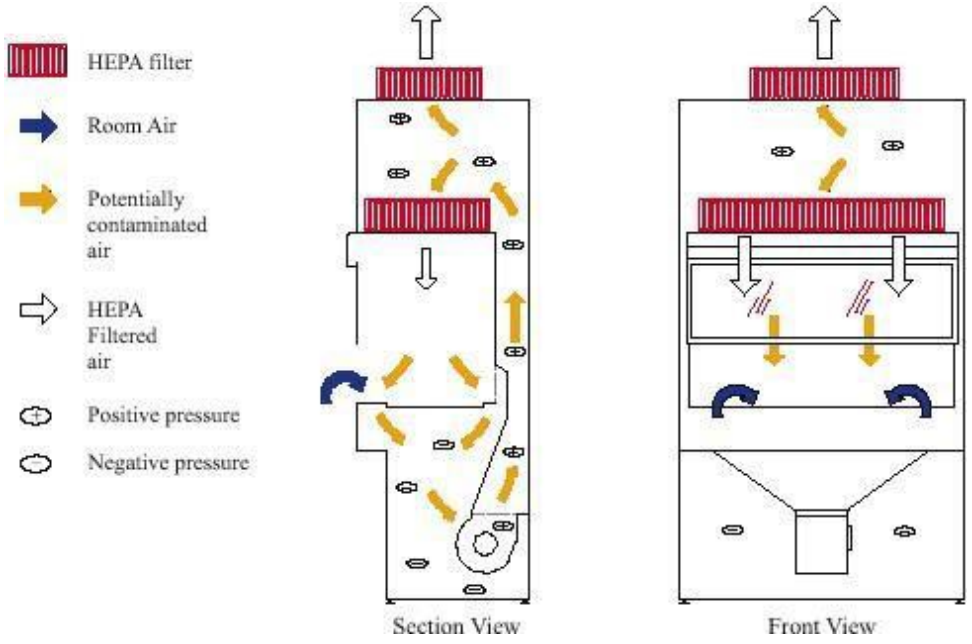
Class II biological safety cabinets are designed to protect the worker, the general public and the product. The airflow velocity at the face of the work opening is at least 75 linear feet per minute (lfpm). Both the supply and the exhaust air are HEPA- filtered. This is the most common class of biological safety cabinets found on campus.

Class I and Class II cabinets are partial containment devices which, if used in conjunction with good laboratory practices, can dramatically reduce the risk of operator exposure to biohazardous material aerosols and droplets.

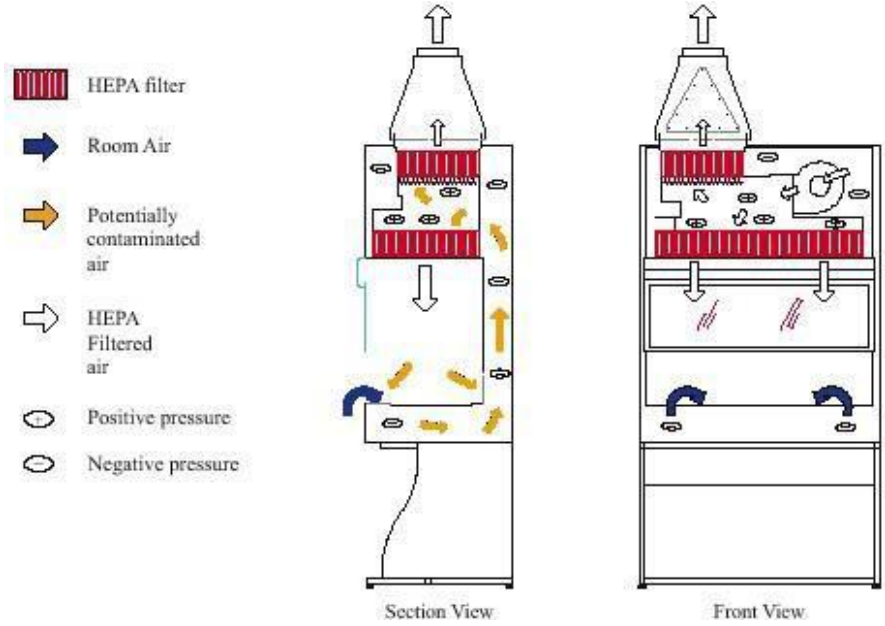
The Class II vertical laminar-flow biological cabinet is an open-front, ventilated cabinet. This cabinet provides a HEPA-filtered, recirculated mass airflow within the workspace. The exhaust air from the cabinet is also filtered by HEPA filters. Thus, the Class II biosafety cabinet will provide personnel, environment, and product protection. While HEPA filters are effective for trapping particulates and infectious agents, these filters will not capture volatile chemicals or gases.

There are four types of Class II cabinets:

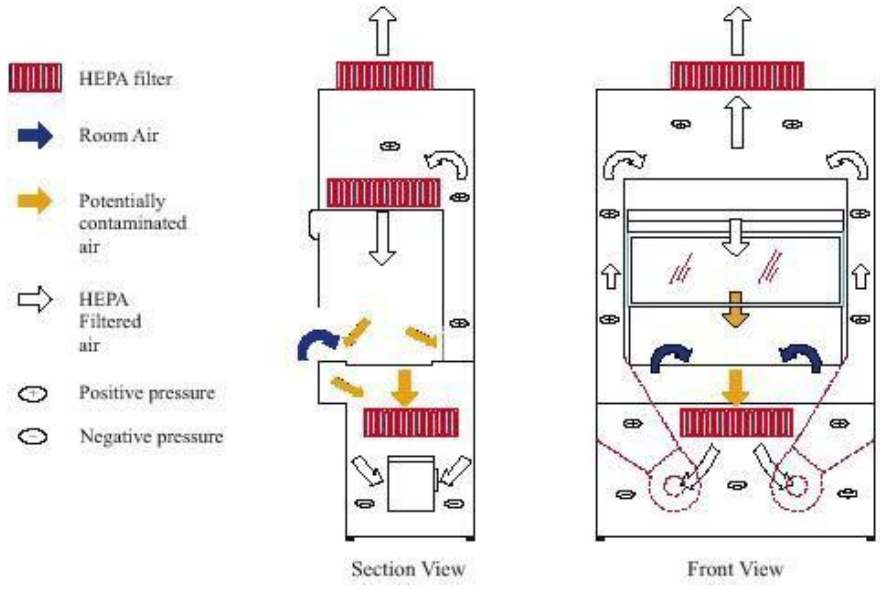
Class II, type A1: this does not have to be vented, which makes it suitable for use in laboratory rooms which cannot be ducted. 30% of the air is exhausted from the cabinet while 70% is recirculated. This cabinet is acceptable for use of low to moderate risk agents in the absence of volatile toxic chemicals and volatile radionuclides. It is important to note that this type of class II cabinet may have a biologically contaminated positive pressure plenum (to the room).



Class II, type A2 or A/B3: this does not have to be vented, which makes it suitable for use in laboratory rooms which cannot be ducted. 30% of the air is exhausted from the cabinet while 70% is recirculated. This cabinet may be used with etiologic agents treated with minute quantities of toxic chemicals and trace quantities of radionuclides that will not interfere with work if recirculated in the downflow air when ducted.

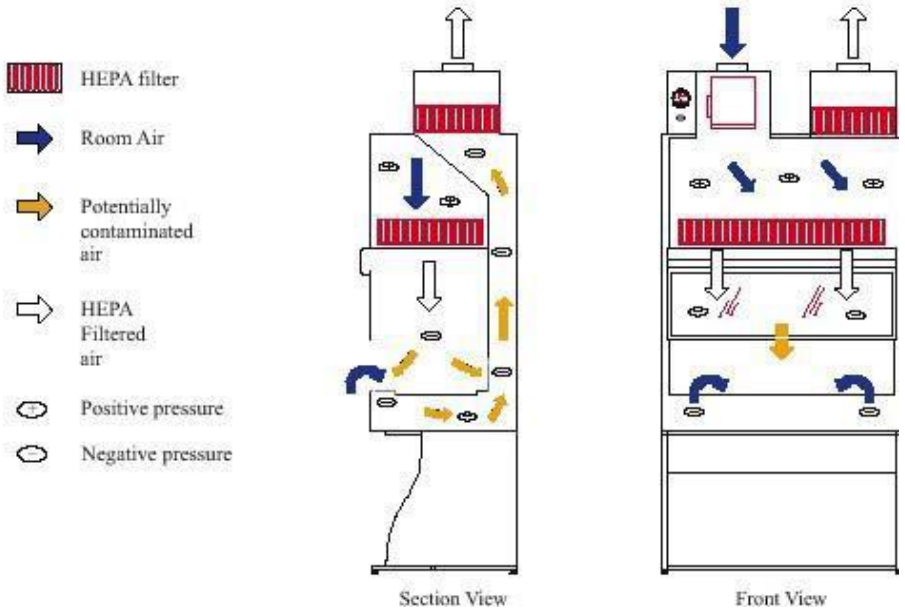


Class II, type B1: this cabinet must be vented, with 60% of the air exhausted from the cabinet while 40% is recirculated back into the cabinet. This cabinet may be used with etiologic agents treated with minute quantities of toxic chemicals and trace amounts of radionuclides required as an adjunct to microbiological studies if work is done in the directly exhausted portion of the cabinet, or if the chemicals or radionuclides will not interfere with the work when recirculated in the downflow air.

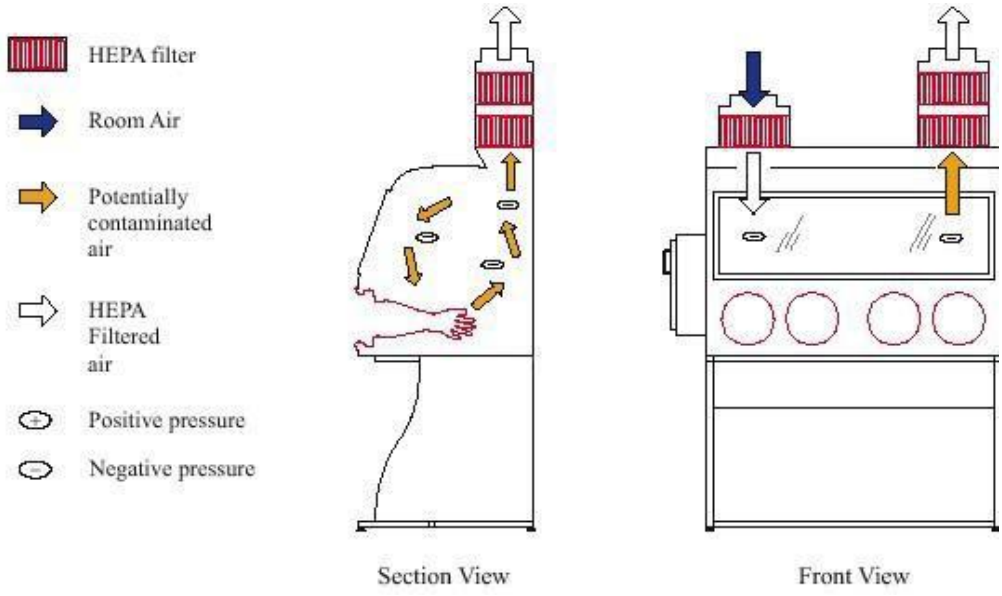


Class II, type B2: this cabinet must be totally exhausted, with 100% of the air exhausted through a dedicated duct. This cabinet may be used with etiologic agents treated with toxic chemicals and radionuclides required as an adjunct to microbiological studies.

Class III biosafety cabinet is a totally enclosed ventilated cabinet of gas-tight construction. Operations



within the Class III cabinet are conducted through attached rubber gloves. When in use, the Class III cabinet is maintained through negative air pressure of at least 0.5 inches water gauge. Supply air is drawn into the cabinet through HEPA filters. The cabinet exhaust air is filtered by two HEPA filters, installed in series, before discharge outside of the facility. The exhaust fan for the Class III cabinet is generally separate from the exhaust fans of the facility's ventilation system.



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.

Proper Use

Start Up

1. Turn off ultraviolet sterilizer (if so equipped) as soon as you enter the room.
2. Check to see if the cabinet has been certified within one year.
3. Turn on all blowers and cabinet illumination lights.
4. Allow five minutes of operation to purge system; check flow alarm system audio and visual alarm function if so equipped.
5. Decontaminate readily accessible interior surfaces with a disinfectant appropriate for the agents or suspected agents present, including the inside of the window sash. If using a 10% bleach solution, remember to do a final wipe down with 70% alcohol or sterilized water to remove any bleach residue.

Shut Down

1. Decontaminate and remove all items from interior work area.
2. Decontaminate readily accessible interior surfaces with a disinfectant appropriate for the agents or suspected agents present, including the inside of the window sash. If using a 10% bleach solution, remember to do a final wipe down with 70% alcohol or sterilized water to remove any bleach residue.
3. Allow five minutes of operation to purge system.
4. Turn on ultraviolet sterilizer if so equipped.
5. Turn off cabinet blower and illumination lights.

Moving/Installation

Biological safety cabinets must be decontaminated prior to moving to protect personnel from any potential exposure to biohazardous materials or infectious agents. In order to ensure filter integrity, the equipment must be recertified after the cabinet is installed at its final new location. Arrangements for this work needs to be made well in advance in order for contractors to meet your schedule. The PI is responsible for contacting the vendor to schedule this work.

Disposal/Salvage/Donation/Relocation off Campus

Decontamination is done by certified professionals. The BSC must be decontaminated prior to filter change, maintenance, disposal, salvage or donation. UCI maintains a service contract with Technical Safety Services (TSS), who can be reached by contacting the information provided on the next page if you need to have your BSC decontaminated prior to it leaving UCI ownership

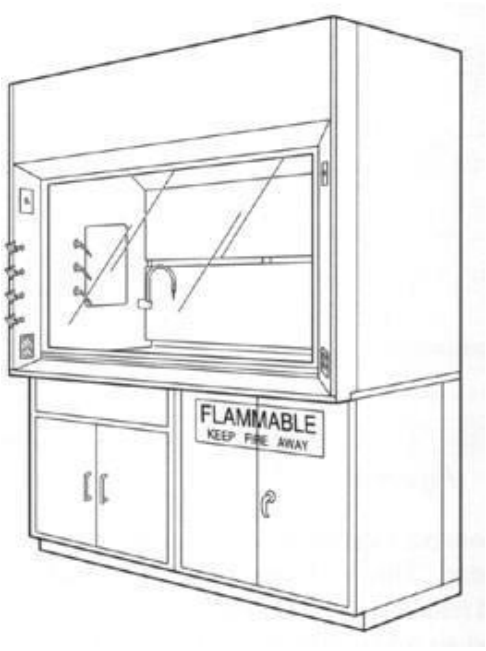
Certification, Maintenance and Repair

It is the PI's responsibility to ensure that all biological safety cabinets used for handling biohazardous materials are **recertified annually**. The UC system-wide Biosafety Cabinet Certification Contract was awarded to Technical Safety Services (TSS).

Technical Safety Services, Inc.
1-800-877-7742
www.techsafety.com

5.12.2 CHEMICAL FUME HOODS

Some lab workers refer to biosafety cabinets as "hoods". It is important to know the difference between a biosafety cabinet and a chemical fume hood. Biosafety cabinets are designed to protect the individual and the environment from biological agents, and to protect the research materials from contamination. Chemical fume hoods, however, are designed solely to protect the individual from exposure to chemicals and noxious gases. Since chemical fume hoods are not equipped with HEPA filters, they must not be used for work with biohazardous materials.



5.12.3 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.

Aerosols are created by practices such as filling centrifuge tubes, removing plugs or caps from tubes after centrifugation, removing supernatant, resuspending sedimented pellets and by the very process of centrifugation. The greatest aerosol hazard is created if a tube breaks during centrifugation. 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 tubes, O-rings and buckets for cracks, chips, erosions, bits of broken glass, etc. Do not use aluminum foil or loose plastic caps to cap centrifuge tubes because it may detach or rupture during centrifugation.
- Fill and open centrifuge tubes, rotors and accessories in a biosafety cabinet (BSC). Avoid overfilling of centrifuge tubes so that closures do not become wet. After tubes are filled and sealed, wipe them down with disinfectant.
- Add disinfectant to the space between the tube and the bucket to disinfect material in the event of breakage during centrifugation.
- Always balance buckets, tubes and rotors properly before centrifugation.
- If the centrifuged specimen contains biohazardous material, open the centrifuge tubes inside a BSC with the tube pointed away from you.

- Do not decant or pour off supernatant. Use a vacuum system with appropriate in- line reservoirs and HEPA filters (For more information, call EH&S.).

- Work in a BSC when resuspending sedimented material. Use a swirling rotary motion rather than shaking. If shaking is necessary, wait a few minutes to permit the aerosol to settle before opening the tube.

- Small low-speed centrifuges may be placed in a BSC during use to reduce the aerosol escape. High-speed centrifuges pose additional hazards. Precautions should be taken to filter the exhaust air from vacuum lines. Manufacturers' recommendations must be meticulously followed to avoid metal fatigue, distortion and corrosion.

- Avoid the use of celluloid (cellulose nitrate) tubes with biohazardous materials. Celluloid centrifuge tubes are highly flammable and prone to shrinkage with age. They distort on boiling and can be highly explosive in an autoclave. If celluloid tubes must be used, an appropriate chemical disinfectant must be used to decontaminate them.

5.12.4 AEROSOL-CREATING 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 leak proof, 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.

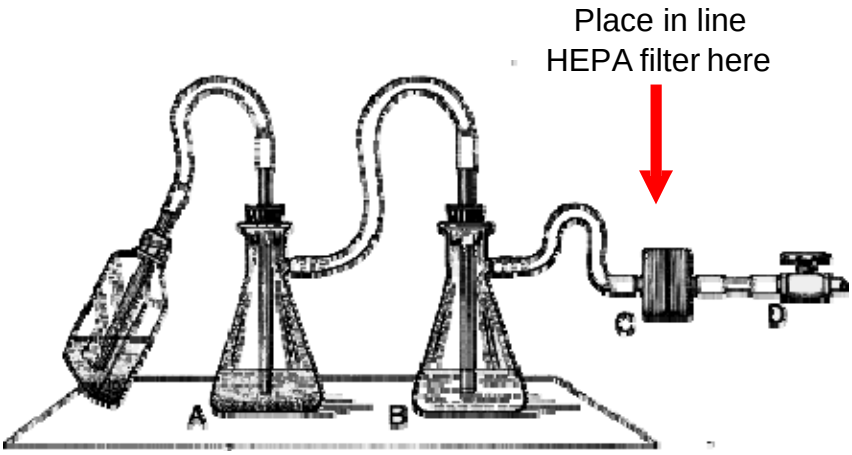
Lyophilizers and ampules: Depending on lyophilizer design, aerosol production may occur when material is loaded or removed from the lyophilizer unit. If possible, sample material should be loaded in a BSC. The vacuum pump exhaust should be filtered to remove any hazardous agents or, alternatively, the 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 ampules 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.

Ampoules used to store biohazardous material in liquid nitrogen have exploded causing eye injuries. The use of polypropylene tubes eliminates this hazard. These tubes are available dust-free and pre-sterilized and are fitted with polyethylene caps and with silicone washers. Heat sealable polypropylene tubes are also available.

5.12.5 PROTECTION OF VACUUM SYSTEMS USED IN TISSUE CULTURE WORK

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 LABORATORY HOUSEKEEPING

Good housekeeping in laboratories is essential to reducing risks and protecting the integrity of biological experiments. Routine housekeeping must be relied upon to provide work areas free of significant sources of contamination. Even though all laboratories are expected to maintain high standards of housekeeping, the standards required of each laboratory is as proportionately high as the BSL designation of the laboratory. Hence, stricter standards are expected of a BSL3 laboratory than they are of a BSL2 laboratory.

Laboratory personnel are responsible for cleaning laboratory benches, equipment and areas that require specialized technical knowledge. Additional laboratory housekeeping concerns include:

- Keep the laboratory neat and free of clutter. Surfaces should be clean and free of infrequently used chemicals, glassware and equipment. Access to sinks, eyewashes, emergency showers and fire extinguishers must not be blocked.
- Properly dispose of chemicals and wastes. Old and unused chemicals should be disposed of promptly and properly. Call EH&S at (949) 824-6200 for details.
- Provide a workplace that is free of physical hazards. Aisles and corridors should be free of tripping hazards. Attention should be paid to electrical safety, especially as it relates to the use

of extension cords, proper grounding of equipment, avoidance of overloaded electrical circuits and avoidance of the creation of electrical hazards in wet areas.

- Autoclaves are high temperature and pressure hazards. Autoclave training is required prior to operating an autoclave. Contact EH&S at (949) 824-6200 to schedule autoclave training.
- Remove unnecessary items on floors, under benches or in corners.
- Properly secure all compressed gas cylinders.
- Never use fume hoods for storage of chemicals or other materials.

5.13.1 PRACTICAL CUSTODIAL CONSIDERATIONS

- Always wet mop. Dry sweeping and dusting may lead to the formation of aerosols.
- Where vacuuming is required, the use of vacuums equipped with high efficiency particulate air (HEPA) filters is recommended in the biological research laboratory. Wet and dry units with HEPA filters on the exhaust are available from a number of manufacturers.

5.13.2 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.

The program consists of installing tamper proof rodent bait stations around the perimeter of the buildings and maintaining them on a regular basis. 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 by (1) Adjusting methods or

inspection/application frequency, (2) Making recommendations for cultural modifications that would discourage these pests from the area. In the event that pests are able to enter a building, Facilities Management staff will respond and determine the cause of any such infestation and indicate what corrective actions are necessary in order to return the building to a pest free environment.

For more information, contact the Integrated Pest Management section of Facilities Management at (949) 824-5444.

5.14 SIGNS

It's important that Principal Investigators, Lab Managers, and SOS Representatives keep their hazard emergency contact information current on the lab door posting.
This lab door posting must be displayed at entrances to laboratories and tissue- culture rooms and updated to reflect biohazards present in the location. UC Irvine has an on- line tool in CiBR-Trac for updating and printing these postings (in color). For more information on how to obtain hazard emergency notification door cards, contact your school EH&S 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.

Medical waste containers must be lined with **RED** biohazard bags. Orange biohazard bags are illegal in California.

Labels, red bags and sharps containers information listing and recommended vendors for UCI can be obtained from the UCI EHS at (949)-824-6200.

Hazard & Emergency Notification

IN CASE OF EMERGENCY DIAL 911 IMMEDIATELY!

Building: Sprague Hall Room(s): 100 Date: 10/18/2011

Contact Name:	Daytime Phone:	Emergency Phone:
Principle Investigator Name	949-824-XXXX	949-824-XXXX
Lab Contact Name	949-824-XXXX	949-824-XXXX

HAZARDS OR SPECIAL CONCERNS (Check)

☐ Toxic Gas	☐ Flammable Gases	☐ Compressed Gases
☐ Cryogenics	☐ Explosives	☐ Pyrophorics
☐ Radioactive Materials or Radiation Producing Machines	☐ Lasers	☐ Flammable Liquids
☒ Oxidizers	☐ Organic Peroxides	☐ Water Reactives
☒ Toxics	☐ Carcinogens	☒ Corrosives
☒ Irritants		

Additional Details:

To update and print additional signs, login using CiBRTrac

5.15 CLEAN AREAS

For the purposes of personnel protection, EH&S prefers that eating, drinking, etc., occur only in separate spaces and will continue to encourage lab designs which allow this. However, when separate space is unavailable, a "Clean Area" may be designated. The Clean Area is that specifically designated portion of the laboratory where the personnel may, if they wish, eat and drink. A "Clean Area" sign must be visibly posted in the designated area.

Note that Clean Areas are not permitted where BSL2+ and BSL3 work are conducted or where Select Agents are being stored or used.

Sections of the lab which are designated Clean Areas must be free not only of biohazards, but also of radiation or chemical contaminants. It is necessary, that such proposed Clean Areas be jointly approved by EH&S personnel from both the Radiation Safety and the Biosafety divisions. Contact EH&S at (949) 824-6200 for posting clean areas.

5.16 LABORATORY MOVES

The laboratory relocation process requires lots of work, planning, a laboratory clearance inspection by EH&S. We must be sure that the laboratory is safe for custodians to clean, contractors to work in, and for the next lab to occupy.

5.16.1 GENERAL GUIDELINES

In preparation for moving, observe the following guidelines:

- Label ALL biohazardous waste bags and sharps containers
- Dispose of ALL biohazardous waste by contacting EH&S for pick up.
- Chemically disinfect liquid biohazardous waste with an EPA approved disinfectant and dispose down the drain with water.

5.16.2 MOVING THE BIOSAFETY CABINET

- Lab must decontaminate biosafety cabinet work surfaces prior to moving them to a new facility. Cabinets used for work with pathogenic organisms at BSL2 or higher (human or primate materials) may require paraformaldehyde decontamination before being moved. Contact EH&S at (949) 824-6200 for instructions or contact TSS at (1-800) 877-7742 to schedule decontamination.
- Each biological safety cabinet must be recertified for correct air flow and filter integrity after it has been moved and placed in its final location to ensure personnel protection. Contact TSS at (1-800) 877-7742 to schedule certification. For more information see **Chapter 11. Laboratory Equipment**.

5.17 BIOHAZARDOUS MATERIAL SPILLS

5.17.1 BIOHAZARD SPILL CLEANUP PROCEDURES

The following procedures are provided as a guideline to biohazardous spill cleanup. In each of the following cases and depending on the size of the spill, notify everyone in the lab and call EH&S at (949) 824-6200. After hours, contact campus police at 911. 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 EH&S immediately for assistance. Only trained personnel should be cleaning up spills.
When cleaning up spills, time is of the essence. Having a spill kit on hand will help minimize the time it takes to clean up.

Protect Yourself

- Avoid direct contact with the spilled material.
- Treat all biological material as if it is infectious.
- Appropriate PPE must be worn. At minimum, disposable gloves, eye protection and a lab coat should be worn. An N95 respirator is advised for spills greater than ~10mL outside a BSC, or any spill inside a centrifuge, because of the likelihood of splashing and/or aerosolization of the biohazardous material.

Contain the Spill

- Cordon off the spill area.
- Do not walk through, or allow others to walk through, the spilled material.
- Everyone not needed for spill cleanup must be cautioned to stay away from the spill area.
- Signs may be posted if necessary.

Disinfect the Spilled Material

- Remove sharps using tools such as tongs or a broom and dustpan and dispose in the appropriate sharps container.
- Absorbent pads or paper towels should be placed over the contaminated surface. A proper disinfectant (this can be a freshly made 10% household bleach solution or a hospital grade disinfectant) must be poured carefully around the edges of the spill with care taken to avoid splashing.
- Working from the outside of the spill toward the center avoids spreading contamination. Try to avoid splashes as you pour.
- After initial cleanup, the spill area must be flooded with disinfectant and left to soak for at least 20 minutes (adequate contact time is important to ensure complete decontamination).
- Disinfectant can be absorbed with paper towels. A final wipe-down should be done with clean paper towels soaked with disinfectant.
- Decontaminate any equipment, walls or other areas likely to have been splashed by the spill.
- *Note:* Alcohol is not recommended as a disinfectant for large spills, especially inside a BSC, because large amounts of alcohol pose an explosion hazard.

Clean Up the Spill

- Sweep up materials and place into plastic, red biohazard bags.
- Any sharp contaminated objects must be removed from the spill area and placed into sharps containers using mechanical means, never with hands.

Dispose of the Material

- Disposable gloves and other protective equipment should be placed in biohazard bags for autoclaving and disposal.
- Contaminated clothing should be placed into bags that are labeled as biohazardous, autoclaved, and commercially laundered.
- All contaminated waste must be disposed as biohazardous waste.

Clean Up

Upon completion, hands must be washed thoroughly with soap and water. Wash hands thoroughly, even if there is no visible contamination.

5.17.2 INSIDE THE BIOSAFETY CABINET (BSC)

1. Allow cabinet to run during cleanup.
2. Wait at least 20 minutes to allow the BSC to contain aerosols.
3. Wear lab coat, safety glasses and gloves during cleanup.
4. Apply 10% bleach and allow a minimum of 20 minutes contact time.
5. Wipe up spillage with disposable disinfectant-soaked paper towel.
6. Wipe the walls, work surface and any equipment in the cabinet with a disinfectant-soaked paper towel to remove bleach residues.
7. Discard contaminated disposable materials using appropriate biohazardous waste disposal procedures (e.g., picked up by EH&S).
8. Place contaminated reusable items in biohazard bags, autoclavable pans with lids or wrap in newspaper before autoclaving and cleanup.
9. Expose non-autoclavable materials to 10% bleach solution for a 20-minute contact time before removal from the BSC. Collect and place in red biohazard waste container for pick up.
10. Remove protective clothing used during cleanup and place in a biohazard bag for autoclaving.
11. Run BSC 20 minutes after cleanup before resuming work or turning off.
12. Report incident to lab supervisor and contact EH&S.

5.17.3 IN THE LAB, OUTSIDE THE BSC

1. Call the Biosafety Officer if the material is BSL2 or greater.
2. Clear area of all personnel. Wait at least 30 minutes for aerosol to settle before entering spill area.
3. Remove contaminated clothing, place in biohazard bag to be autoclaved.
4. Put on a disposable gown, safety glasses and gloves.
5. Pick up sharps using tools and place in appropriate sharps container.

6. Initiate cleanup with disinfectant as follows:

   i. Place dry paper towel on spill (to absorb liquids); then layer a second set of disinfectant soaked paper towels over the spill.
   ii. Encircle the spill with additional 10% bleach solution being careful to minimize aerosolization while assuring adequate contact.
   iii. Decontaminate all items within the spill area.
   iv. Allow 20 minutes contact time to ensure germicidal action of disinfectant.
   v. Wipe equipment with appropriate disinfectant.
   vi. Discard contaminated disposable materials using appropriate biohazardous waste disposal procedures (picked up by EH&S).
   vii. Decontaminate reusable items.

7. Place contaminated reusable items in biohazard bags, autoclavable pans with lids or wrap in newspaper before autoclaving and cleanup.

8. Expose non-autoclavable materials to 10% bleach solution for a 20-minute contact time. Collect and place in red biohazard waste container for pick up through EH&S.

9. Remove protective clothing used during cleanup and place in a biohazard bag for autoclaving.

10. Report incident to lab supervisor and contact EH&S.

5.17.4 INSIDE A CENTRIFUGE

1. Call the Biosafety Officer if the material is BSL2 or greater.

2. Clear area of all personnel.

3. Wait 30 minutes for aerosol to settle before attempting to clean up spill.

4. Wear a lab coat, safety glasses and gloves during cleanup, and possibly respiratory protection depending on the agent.

5. Remove rotors and buckets to nearest biological safety cabinet for cleanup.

6. Thoroughly decontaminate inside of centrifuge by soaking all pieces within a disinfectant solution for at least 20 minutes.

7. Discard contaminated disposable materials using appropriate biohazardous waste disposal procedures (picked up by EH&S).

8. Place contaminated reusable items in biohazard bags, autoclavable pans with lids or wrap in newspaper before autoclaving and cleanup.

9. Expose non-autoclavable materials to 10% bleach solution for a 20-minute contact time before removal from the BSC. Collect and place in red biohazard waste container for pick up.

10. Remove protective clothing used during cleanup and place in a biohazard bag for autoclaving.

11. Report incident to lab supervisor and contact EH&S.

5.17.5 OUTSIDE THE LAB, IN TRANSIT

Acceptable Example

Acceptable Example

- Transport labeled biohazardous material in an unbreakable, well-sealed primary container placed inside of a second unbreakable, lidded container (cooler, plastic pan or pail) labeled with the Biohazard symbol.
- Call EH&S at (949) 824-6200 to assist in cleanup.
- Should a spill occur in a public area, do not attempt to clean it up without appropriate personal protective equipment.
- Secure the area, keeping all people well clear of the spill.
- Standby during spill response and cleanup activity and help only as requested or as necessary.

5.18 DECONTAMINATION AND DISINFECTION

5.18.1 DEFINITIONS

Decontamination is a term used to describe a process or treatment that renders a medical device, instrument, or environmental surface safe to handle. A decontamination procedure can range from cleaning with soap and water to sterilization. Sterilization, disinfection, and antisepsis are all forms of decontamination.

Sterilization is the use of a physical or chemical procedure to destroy all microbial life, including highly resistant bacterial endospores.

Disinfection eliminates virtually all pathogenic non-spore forming microorganisms but not necessarily all microbial forms on inanimate objects (e.g., work surfaces and equipment). Effectiveness is influenced by the kinds and numbers of organisms, the amount of organic matter, the object to be disinfected and chemical exposure time, temperature and concentration.

Antisepsis is the application of a liquid antimicrobial chemical to skin or living tissue to inhibit or destroy microorganisms. It includes swabbing an injection site on a person or animal and hand washing with germicidal solutions.

5.18.2 GENERAL PROCEDURES

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.

5.18.3 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. Each category is discussed briefly below.

Heat

Wet Heat

Wet heat is the most dependable method of sterilization. Autoclaving (saturated steam under pressure of approximately 15 psi to achieve a chamber temperature of at least 250°F for a prescribed time) is the most convenient method of rapidly achieving destruction of all forms of microbial life. In addition to proper temperature and time, prevention of entrapment of air is critical to achieving sterility. The material to be sterilized must come in contact with steam and heat. Chemical indicator (e.g., autoclave tape) must be used with each load placed in the autoclave. The use of autoclave tape alone is not an adequate monitor of efficacy. Autoclave sterility monitoring must be conducted at least monthly using appropriate biological indicators (Bacillus stearothermop throughout the autoclave. The spores, which can survive in 13 minutes, are more resistant to heat than most, ther when validating decontamination procedures. Each type of container employed should be spore tested because efficacy varies with the load, fluid volume, etc. **The wet heat method is not an approved method to decontaminate biohazardous waste at UCI.**

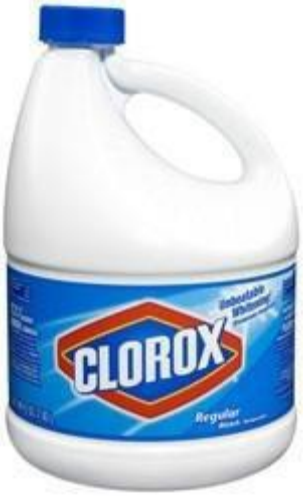
Dry Heat

Dry heat is less efficient than wet heat and requires longer times and/or higher temperatures to achieve sterilization. It is suitable for the destruction of viable organisms on impermeable non-organic surfaces such as glass, but it is not reliable in the presence of shallow layers of organic or inorganic materials which may act as insulation. Sterilization of glassware by dry heat can usually be accomplished at 160- 170 degrees Centigrade for periods of 2-4 hours. Dry heat sterilizers should be monitored on a regular basis using appropriate biological indicators [spore strips].
The dry heat method is not an approved method to decontaminate biohazardous waste at UCI.

Incineration

Incineration is another effective means of decontamination by heat. As a disposal method, incineration has the advantage of reducing the volume of the material prior to its final disposal.
However, there are no incinerators here at UCI.

Liquid Disinfection



The most practical use of liquid disinfectants is for surface decontamination and, when used in sufficient concentration, as a decontaminate for liquid wastes prior to final disposal in the sanitary sewer. If liquid disinfectants are used, they must have been shown to be effective against the organism(s) present. Liquid disinfectants are available under a wide variety of trade names. In general, these can be classified as: halogens, acids, alkalis, heavy metal salts, quaternary ammonium compounds, phenolic compounds, aldehydes, ketones, alcohols and amines. The more active a compound is, the more likely it is to have undesirable characteristics such as corrosivity. No liquid disinfectant is equally useful or effective under all conditions and for all viable agents.

Vapors and Gases

Vapors and gases are primarily used to decontaminate biological safety cabinets and associated systems; bulky or stationary equipment not suited to liquid disinfectants; instruments or optics which might be damaged by other decontamination methods; and rooms, buildings and associated air-handling systems. Agents included in this category are glutaraldehyde and formaldehyde vapor, ethylene oxide gas, peracetic acid and hydrogen peroxide vapor. When used in closed systems and under controlled conditions of temperature and humidity, excellent disinfection can be obtained. Great care must be taken during use because of the hazardous nature of many of these compounds. Contact EH&S for monitoring requirements if these compounds are to be used.

Radiation

Although ionizing radiation will destroy microorganisms, it is not a practical tool fc
Nonionizing radiation in the form of ultraviolet radiation (UV) is used for inactivating viruses, bacteria, and fungi. It will destroy airborne microorganisms and inactivate micro-organisms on exposed surfaces or in the presence of products of unstable composition that cannot be treated by conventional means. Because of the low penetrating power of UV, microorganisms inside dust or soil particles will be protected from its action, limiting its usefulness. UV is used in air locks, animal holding areas, ventilated cabinets, and laboratory rooms to reduce levels of airborne microorganisms and maintain good air hygiene. UV can cause burns to the eyes and

skin of people exposed for even a short period of time. Therefore, proper shielding should be maintained when it is in use. UV lamps that are used for space decontamination should be interlocked with the general room or cabinet illumination, so that turning on the lights extinguishes the UV. UV lamps are not recommended for decontamination unless they are properly maintained. Due to the fact that UV lamp intensity or destructive power decreases with time, it should be checked monthly with a UV meter or monitoring strip. Frequent cleaning every few weeks is necessary to prevent accumulation of dust and dirt on the lamp which also reduces its effectiveness drastically. If UV must be used, it should be used when areas are not occupied. The American Biological Safety Association has distributed a position paper on this topic and does not recommend UV lights to be used within biosafety cabinets.

5.19 BIOSAFETY LEVEL 3 LABORATORIES

** **In progress – BSL3 Biosafety Manual and SOPs** **

5.20 LABORATORY INSPECTION

5.20.1 EH&S LABORATORY AND BUILDING AND SAFETY SURVEY (LBSS)

In addition to biosafety inspections related to IBC protocols, EH&S conducts scheduled inspections of laboratories on a regular basis. Inspections are not limited to biosafety, but encompass chemical, electrical, fire and general safety issues.

Some aspects of a typical inspection include:

Laboratory Identification

1. PI's name, department, building, room number, lab manager, phone, mail code, email, etc.
2. Biohazardous materials: prions; genomic sequences; virioids; viruses; rickettsiae/chlamydia; bacteria; parasites; plants/plant, pathogens; animals; human or primate blood; human body fluids, cells and tissues
3. IBC approval review facility inspections
4. Emergency call-list

Facility/Equipment Review

1. Airflow from lower-hazard to higher-hazard areas
2. Designated clean areas
3. Any hazardous material in designated clean area
4. Neat or cluttered work areas
5. Biosafety cabinet information: make, model, size, number
6. Biosafety cabinet certification: certified annually
7. Decontamination of biosafety cabinet before use
8. Decontamination of biosafety cabinet after use
9. Neat or cluttered grate in biosafety cabinet
10. Neat or cluttered work area in biosafety cabinet
11. HEPA filter on vacuum line
12. Liquid media decontaminated
13. Spill-kit availability

Work Practices

1. Aerosol-generating procedures and steps taken to control them
2. Effective use of biosafety cabinets
3. Surface decontamination: disinfectant used, contact time, frequency

4. Wearing proper personnel protective equipment
5. Any evidence of eating in the lab areas

Hazard Communication

1. Hazard Emergency Notification placard posted at entrance to the lab
2. Is the Exposure Control Plan complete?
3. Understand additional risk for immunodeficient individuals
4. Appropriate biosafety cabinet signage (Biohazard placard for BSCs in which biohazards are used and a "Not for use with Biohazards" sign for those BSCs in which no biohazards are used)
5. Review of training records and date of last training

Biohazard Waste Handling

1. Labeled rigid containers with lids containing red biohazard bags
2. Transportation of biohazardous waste
3. Only biohazard waste in biohazard bags
4. Sharps containers not overfilled

Interview

1. Biosafety knowledge
2. Hazards of materials in their work
3. Waste disposal practices
4. Special precautions, practices, or procedures
5. Personal protective equipment
6. Emergency response procedures/ Post exposure management

5.20.2 REGULATORY AGENCY INSPECTION

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

5.21 HANDLING BIOHAZARDOUS AND MEDICAL WASTE

5.21.1 DEFINITIONS BIOHAZARDOUS WASTE

A. 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.

B. 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 so as to drip from the article, that contaminated article may be treated as "Medical Solid Waste" (see below).

- 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 bythe administering agency or the local Health Officer to pose a threat to human health or the environment.

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. Environmental Health and Safety provides the following guidelines for medical waste:

Please note: Contact EH&S at (949) 824-6200 or visit our website at www.ehs.uci.edu if you need additional information regarding medical/biohazardous waste.

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.

Summary of Requirements for BSL-1 Biohazardous Waste

A. Insert a white or clear biohazard bag inside a rigid container and fold the edges over the lip of the container (Note: orange bags may not be used for any purpose).

B. Place only biohazardous material in this container (It must not be used for disposing of normal trash or sharps). Place sharps only in "sharps containers" designed specifically for that purpose.

C. Keep a lid on the biohazardous materials waste container except when it is specifically in use.

D. 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.

E. All biohazardous waste must be marked with "Biohazardous Waste" (or the biohazard symbol).

F. Biohazardous waste transported outside the room of generation must be double bagged AND placed inside a rigid, leak-proof container with a leak- proof lid.

G. Sharps (needles, glass pipettes, blades, etc.) must be placed in a rigid, puncture-resistant, tamper-proof container and labeled with the same information as in item E. above.

H. All biohazardous waste must be decontaminated prior to disposal, either by autoclaving

or chemical disinfection. Once decontaminated, BSL-1 waste that is not related to recombinant DNA research can be disposed in the regular trash.

Summary of Requirements for Medical Waste

A. Insert a RED biohazard bag inside a rigid container and fold the edges over the lip of the container. Place a second red bag inside the first so that biohazardous material waste will be double bagged (Note: orange bags may not be used for any purpose.).

B. Place only biohazardous material in this container (It must not be used for disposing of normal trash or sharps.). Place sharps only in "sharps containers" designed specifically for that purpose.

C. Keep a lid on the biohazardous materials waste container except when it is specifically in use.

D. 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.

E. All biohazardous waste must be marked with "Biohazardous Waste" or the international biohazard symbol.

F. Biohazardous waste transported outside the room of generation must be double bagged AND placed inside a rigid, leak-proof container with a leak- proof lid.

G. Sharps (needles, glass pipettes, blades, etc.) must be placed in a rigid, puncture-resistant, tamper-proof container and labeled with the same information as in item E above.

H. All medical waste must be decontaminated prior to disposal. At UCI, medical waste is not treated on-site; all medical waste is picked up by EH&S and sent to an approved medical waste vendor.

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). For more information on the MWMA visit:

https://www.cdph.ca.gov/Programs/CEH/DRSEM/CDPH%20Document%20Library/EMB/MedicalWaste/MedicalWasteManagementAct.pdf

5.21.2 STORAGE AND CONTAINMENT

Storage

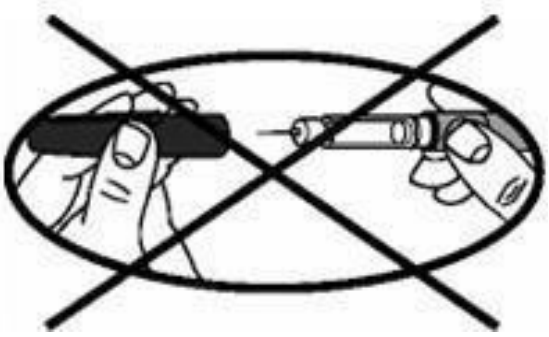
Segregate from other waste at point of origin (biohazard/medical waste vs. chemical waste vs. radioactive waste). Storage for untreated, bagged biohazardous waste must be secured to deny access to unauthorized personnel. Exterior doors must be marked in both English and Spanish:

Maximum storage time:

7 days or less when stored above the temperature 32° F OR 90 days or less when stored below 0°C.

Sharps

- Needles and syringes shall not be clipped, bent, broken, sheared or recapped prior to disposal.
- Sharps must be disposed of in containers which are leak-proof, rigid, puncture- resistant and "tamper-proof" (made so that they cannot be reopened without great difficulty).
- Sharps containers must be labeled with "Biohazard" or "Infectious Waste," and the international biohazard symbol.



Transportation

Any time biohazardous or medical waste is moved outside the room in which it was generated, the material shall be transported in a closed, rigid secondary container as described below.

Secondary Containers

- All white or red bags and sharps containers must be placed in secondary rigid containers such as pails, drums, dumpsters or bins for storage.

- Secondary containers must be leak-proof and have tight-fitting covers.
- Secondary containers must be labeled on the lid and sides with the words,

  "Infectious Waste," or with the international biohazard symbol and the word "Biohazard."
- Reusable secondary containers must be easy to clean and must be washed and decontaminated each time they are emptied, unless they have been completely protected from contamination.

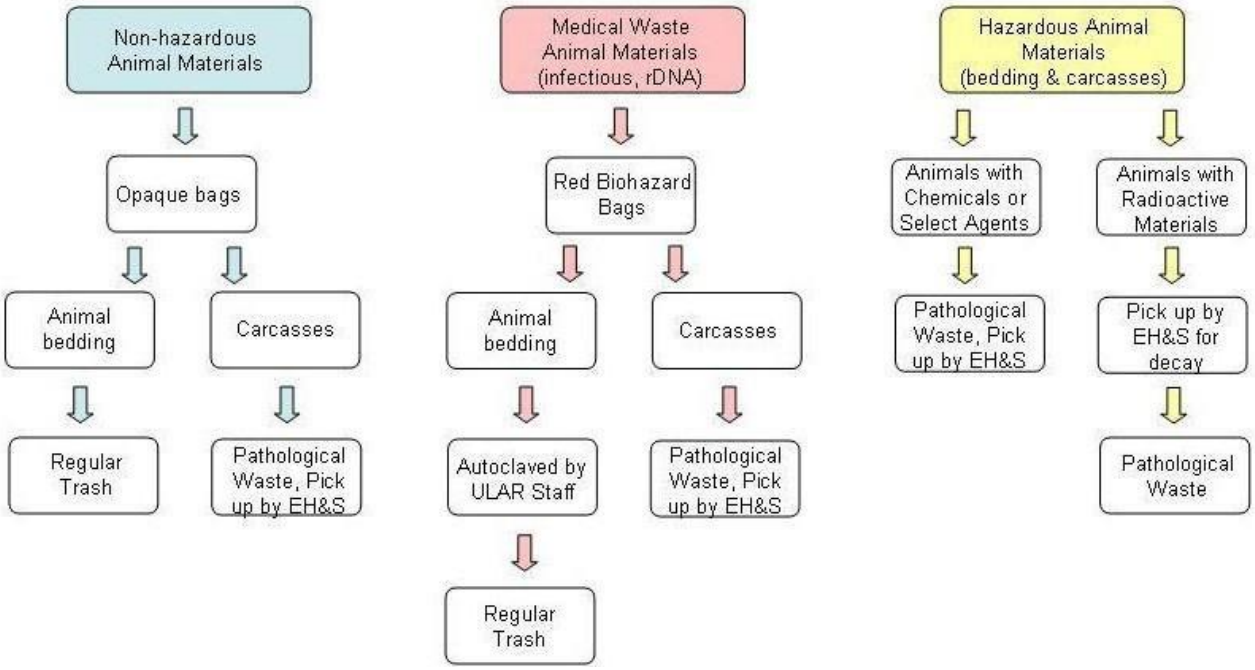
5.21.3 DISPOSAL OF BIOHAZARDOUS/MEDICAL WASTE

Medical Waste

Medical waste must be disposed of in one of the following methods:

1. Discharge into approved sewer system (liquids and semi-liquids only) after decontamination. Chemicals other than bleach may not be poured into the sewer.
2. Disposal off-campus at a state-approved autoclave or incinerator.
3. Recognizable Human Anatomical remains – Willed Body Program: Recognizable human anatomical remains must be cremated or interred. Consult the School of Medicine Willed Body Program for further information.
4. Animal Carcass disposal: Research animals containing infectious agents must be disposed as medical pathological waste. **All animal carcasses on campus are treated as pathological waste.**

For definitions of hazardous waste visit: https://www.ehs.uci.edu/programs/enviro/



Hazardous Waste Collection Request

To request EH&S pick up of hazardous waste, send a request by visiting http://www.ehs.uci.edu/programs/enviro/ and completing the appropriate waste collection form online.

Disinfecting Tissue Culture Media in Vacuum Flasks

Use this standard operating procedure developed by UCSD for disinfecting tissue culture media:

http://blink.ucsd.edu/safety/research-lab/biosafety/decontamination/flasks.html

Autoclaving

Autoclaving to render the waste noninfectious is the primary method used at UCI to treat biohazardous waste before disposal. Autoclaved waste shall be disposed of as Medical Solid Waste provided it does not contain any other hazardous properties (e.g., radioactivity). Operating procedures for steam sterilizers must include, but not be limited to, the following:

5. 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.

6. 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.

7. 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.
8. 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.

9. Training by EH&S.

5.21.4 MEDICAL WASTE MANAGEMENT PLAN

The UCI Medical Waste Management Plan can be provided on request. Contact EH&S at 949-824-

6200.

5.22 INFECTIOUS AGENT AND BIOHAZARDOUS MATERIAL SHIPPING

PROGRAM DESCRIPTION

It is a requirement of the University of California, Irvine (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 (EH&S) or personnel within the school who are trained specifically to package these materials. For questions please contact EH&S at (949) 824-6200.

5.22.1 SCOPE OF PROGRAM

The Department of Transportation (DOT) Hazardous Materials Shipping Regulations 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.

5.22.2 DEFINITIONS

49 CFR - Code of Federal Regulations published by the United States Department of Transportation. These regulations govern all modes of transport of dangerous goods/hazardous materials to/from or within the United States and its territories.

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 id 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 means 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, secreta, 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. See 3.6.2.1.2 of the IATA Dangerous Goods Regulations.

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 World Health Organization (WHO) 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. The criteria for each risk group according to the level of risk are as follows:

Risk Group Table

Risk group	Pathogen	Risk to individuals	Risk to the community
4	A pathogen that usually causes serious human or animal disease that can be readily transmitted from one individual to another, directly or indirectly, and for which effective treatments and preventive measures are not usually available	HIGH	HIGH
3	A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another, and for which effective treatments and preventive measures are available.	HIGH	LOW
2	A pathogen that can cause human or animal disease but is unlikely to be a serious hazard, and, while capable of causing serious infection on exposure, for which there are effective treatments and preventive measures available and the risk of spread of infection is limited.	MODERATE	LOW
1	A micro-organism that is unlikely to cause human or animal disease. A material containing only such micro-organisms is not subject to the requirements of this subchapter.	NONE OR LOW	NONE OR LOW

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

Dangerous Goods/Hazardous Materials (HAZMAT) - Articles or substances which are capable of posing 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.

5.22.3 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 EH&S 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 EH&S to assist in the oversight of packaging and shipping hazardous materials and dangerous goods by the shipper.

5.22.4 SPECIFIC PROGRAM COMPONENTS

Requirements for Biohazardous Materials, Diagnostic Specimens, or Infectious Agents:

Infectious Substance Shipments by Ground:
Shipments of infectious substances by ground must comply with the Department of Transportation Hazardous Materials: Revision to Standards for Infectious Substances and Genetically Modified Micro-organisms

https://www.phmsa.dot.gov/transporting-infectious-substances/transporting- infectious-substances-safely

UCI Requirements for Air Transportation of Infectious Substances, Cultures and Stocks, Toxins, Genetically Modified Micro-organisms or Diagnostic Specimens:
Any person preparing Infectious Substances or Diagnostic Specimens for Shipment by Air, including all Federal Express Shipments must complete training every 2 years or any time the regulations change. Training is provided by contacting EH&S.

For shipment of CDC Select Agents or USDA High Consequence Pathogens, including Infectious Agents or Biological Toxins laboratories must contact EH&S High Containment Director or Biosafety Office prior to shipping or receiving Select Agents or BSL3 agents.

UCI Requirements for Shipment of Insects

Many carriers are no longer accepting insects for shipment. In addition, importation or exportation of insects may require a permit from USDA APHIS.

For questions regarding biohazardous materials, infectious substance, and diagnostic specimens, insect or Select Agent shipments please contact the Biosafety Officer at (949) 824-6200.

Import/Export Permit Information for Etiologic Agents or Insects

Many etiologic agents, infectious materials or vectors containing infectious agents are imported from foreign locations into the United States for domestic use (educational, scientific, commercial, etc.). Packages containing etiologic agents or vectors originating in these foreign locations must have an importation permit issued by the United States Public Health Service. Importation permits are issued only to the importer, who must be located in the United States. The importation permit, with the proper packaging and labeling, will expedite clearance of the package of infectious materials through the United States Public Health Service Division of Quarantine and release by U.S. Customs.

The United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Veterinary Services (VS) regulates the importation of animals and animal-derived materials to ensure that exotic animal and poultry diseases are not introduced into the United States. Generally, a USDA veterinary permit is needed for materials derived from animals or exposed to animal-source materials. Materials which require a permit include, animal tissues, blood, cells or cell lines of livestock or poultry origin, RNA/DNA extracts, hormones, enzymes, monoclonal antibodies for IN VIVO use in non-human species, certain polyclonal antibodies, antisera, bulk shipments of test kit reagents, and microorganisms including bacteria, viruses, protozoa, and fungi. Exceptions to this requirement are human and non-human primate tissues, serum, and blood. Various other animal materials which require a permit include dairy products (except butter and cheese), and meat products (e.g., meat pies, prepared foods) from countries with livestock diseases exotic to the U.S. Import permit applications may be obtained online at the APHIS Import Authorization System.

Importation permits are issued by the Office of Health and Safety at the Centers for Disease Control and Prevention after review of a completed application form. The regulation, application, and instructions can be found online at CDC Importation Permit Application.

Chemical Shipments:

Shipment of hazardous materials by ground must comply with strict DOT regulations.

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).

Noncompliance with proper shipping procedures can pose health and safety risks that may carry civil and/or criminal liability. Shipping of hazardous materials must be coordinated with the UCI Environmental Health and Safety Office.

5.22.5 REPORTING REQUIREMENTS

Please contact EH&S 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.

5.22.6 INFORMATION AND EXTERNAL SOURCES

- ABSA Guidelines for the Safe Transport of Infectious Substances andDiagnostic Specimens
- Hazmatpac (800) 923-9123
  Packaging supplies for hazardous materials transportation
- Centers for Disease Control and Prevention: (404) 639-3238 Importation Permits for Etiologic Agents: Import Permit Program
- Centers for Disease Control and Prevention, OHS Interstate Shipment of Etiologic Agents
- 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
- LabelMaster: (800) 621-5808 For packaging material and labels
- Thermosafe Brands: (800) 323-7442
  Packaging materials for shipping products with dry ice
- Saf-T-Pak: (800) 814-7484
  For packaging material information and advice on how to ship infectious substances
- UPS Guide for Transporting Hazardous Materials
  UPS Hazardous Materials Support Center (800) 554-9964

5.22.7 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 http://www.ehs.uci.edu/programs/dgoods/index.html or contact the UCI EHS at (949) 824-6200.

5.22.8 SHIPPING DANGEROUS AND HAZARDOUS MATERIALS

For more information regarding the shipping of dangerous or hazardous materials, visit: http://www.ehs.uci.edu/programs/dgoods/index.html

5.22.9 SUSPICIOUS PACKAGES

For guidance on handling suspicious packages, visit: http://www.ehs.uci.edu/programs/ih/SuspiciousPackage8152003.pdf

5.23 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)

5.23.1 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: http://www.selectagents.gov/SelectAgentsandToxinsExclusions.html. Some select toxins are exempt based on the total amount that the lab will possess at any time.
Please review the table of Select Toxins with their exempt quantities

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 EH&S 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 stains of Junin virus (Candid #1), Rift Valley fever virus (MP-12), and Venezuelan Equine encephalitis virus vaccine strain TC-83 and other attenuated strains.

5.23.2 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.

5.23.3 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.

5.23.4 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

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 https://osp.od.nih.gov/biotechnology/faqs-on-incident-reporting/ ,the incident will be reported to the NIH.

UCI MEDICAL TREATMENT

CALL 911 FOR ANY IMMEDIATE OR LIFE THREATENING INJURIES

NEWPORT URGENT CARE (949) 752-6300

LOCATED OFF CAMPUS (BRISTOL AND JAMBOREE)
1000 BRISTOL STREET NORTH, SUITE 1-B, NEWPORT BEACH
MON-FRI 8:00 AM - 9:00 PM;
SAT & SUN 8:00 AM - 8:00 PM

AFTER HOURS: CALL NEWPORT URGENT CARE FOR AFTER-HOURS PHYSICIAN
OR GO TO ANY EMERGENCY ROOM

WORK RELATED INJURIES

SERIOUS WORK-RELATED INJURIES REQUIRING HOSPITALIZATION: CONTACT EH&S IMMEDIATELY (949) 824-6200

ALL WORK-RELATED INJURIES MUST BE REPORTED VIA THE ONLINE INCIDENT FORM AVAILABLE AT THE EH&S WEBSITE WWW.EHS.UCI.EDU UNDER "REPORT AN INJURY/SAFETY CONCERN" OR HUMAN RESOURCES WEBSITE UNDER WORKERS COMPENSATION OR CALL (949) 824-9152 or (949) 824-0500

FOR MEDICAL AUTHORIZATION
DURING WORK HOURS: UCI WORKERS' COMPENSATION (949) 824-9152 or (949) 824-0500
WHEN WORKERS' COMPENSATION IS NOT AVAILABLE, THE EMPLOYEE'S SUPERVISOR MAY GRANT AUTHORIZATION

ALTERNATE LOCATIONS

STUDENT HEALTH CENTER (949) 824-5304
EAST PELTASON AND PEREIRA
MON-FRI 7:30 AM-5:30 PM
FIRST AID TREATMENT ONLY
GRADUATE AND UNDERGRADUATE STUDENTS ONLY

OCCUPATIONAL HEALTH CLINIC
(714) 456-8300
UCI MEDICAL CENTER PAVILION III, BUILDING 29
MON-FRI 7:30 AM-5:30 PM,
CLOSED SAT & SUN
AFTER HOURS - GO TO UCIMC EMERGENCY ROOM

KAISER OCCUPATIONAL HEALTH CENTER (OFF CAMPUS)

IRVINE, (949) 932-5899
SANTA ANA, (714) 830-6660

MEMORIAL OCCUPATIONALMEDICAL SERVICES,
(562) 933-0085
(LOCATED AT LONG BEACH MEMORIAL HOSPITAL

SERVICES PROVIDED AT NEWPORT URGENT CARE TO GRADUATE OR UNDERGRADUATE STUDENTS WILL BE CHARGED TO THEIR INSURANCE (PRIVATE, GSHIP, OR USHIP). PLEASE RETAIN RECEIPT FOR PROOF OF VISIT AND POTENTIAL REIMBURSEMENT.

7.0 RFERENCES

Cal/OSHA §5193. Bloodborne Pathogens. **https://www.dir.ca.gov/title8/5193.html**
Cal/OSHA §5199. Aerosol Transmissible Diseases. **https://www.dir.ca.gov/title8/5199.html**

CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition
https://www.cdc.gov/labs/BMBL.html

CDC/USDA Federal Select Agent Program

NIH Guidelines for research involving recombinant or synthetic nucleic acid molecules (NIH Guidelines) April 2019. Department of Health and Human Services National Institutes of Health https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf

Public Health Agency of Canada Pathogen Safety Data Sheet: https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment.html