

UNIVERSITY OF CALIFORNIA
UC RIVERSIDE

Environmental
Health & Safety

BIOSAFETY MANUAL



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1.0 ABOUT UCR's BIOSAFETY PROGRAM

1.1 Purpose

The purpose of the Biosafety Program is to safeguard all employees, students, the community and the environment from exposure to biologically hazardous materials or agents being used at UCR that may cause disease or be harmful to humans. This manual provides a comprehensive overview of proper work practices, regulations, and requirements for proper containment and disposal of biological hazards.

1.2 Scope

All UCR Principal Investigators (PIs) and laboratory workers should adhere to these biological safety policies and procedures in the conduct of their research and in the management of their laboratories.

2.0 ROLES AND RESPONSIBILITIES

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

Federal law requires the establishment of an Institutional Biosafety Committee (IBC) at institutions with research involving recombinant or synthetic nucleic acid molecules, potentially infectious organisms (human, plant, arthropod, toxins), and human-derived materials. At UCR, the IBC is appointed by the Vice Chancellor for Research and Economic Development (VC-RED) under the auspices of Office of Research Integrity (ORI). Administrative support for the IBC is provided by the office of VC-RED. The IBC consists of at least five individuals: two community members who are not affiliated with UCR, an appropriate recombinant or synthetic DNA expert, a plant and animal expert, and the Biosafety Officer. The IBC membership represents collective expertise and research experience in recombinant DNA, infectious agents, biological toxins, and animal research which are applied to the evaluation of appropriate safety measures needed for experiments that may pose potential risks to health or the environment.

The IBC is responsible for:

- (1) Ensuring that research conducted at UCR is in compliance with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (hereinafter as "NIH Guidelines")*
- (2) Drafting and establishing campus biosafety policies and procedures for proper handling of biohazardous materials
- (3) Reviewing individual research proposals for biosafety concerns.

The IBC meets monthly to review proposals from faculty.

ENVIRONMENTAL HEALTH AND SAFETY (EH&S)

UCR EH&S:

- Monitors compliance with university policies, CDC, NIH, OSHA, and state criteria regarding the use of potentially infectious materials.
- Advises on appropriate safe work practices and procedures; containment controls; safety training; and personal protective equipment required for experimental protocols.
- Reviews and approves the use and transfer of biohazardous materials by PIs and setting safety criteria for the use of these agents.
- Provides training for proper handling, storing, disposing, and transporting of biohazardous materials in pursuant to regulatory requirements
- Conducts periodic inspections of laboratories to ensure practices and procedures are rigorously followed.
- Develops emergency plans for handling accidental spills and personnel contamination.
- Investigates all reported accidents which may result in personnel or environmental exposure to biohazardous materials.
- Attends IBC meetings to present current status of BUAs being reviewed.
- In consultation with faculty, staff and the IBC, develops and implements 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.
- Corresponds with all applicable regulatory agencies.

PRINCIPAL INVESTIGATOR (PI)

The Principal Investigator (PI) is directly and primarily responsible for the safe operation of their laboratory, and for compliance by all their laboratory personnel with all UCR biosafety policies and procedures. The PI's knowledge and judgement are critical in assessing risks and appropriately applying campus biosafety guidelines.

The PI is responsible for the following:

- He/She will not initiate research using infectious agents, human blood or tissues, toxin, or recombinant DNA (rDNA) unless all the applicable requirements outlined in this manual are met.
- He/She will consult and refer to NIH Guidelines and CDC's BMBL 5th Edition to determine the appropriate Risk Group classification of the microorganisms to be used,

and that they will use the prescribed microbiological practices and laboratory techniques required by the biosafety level assigned to their work by the IBC.

- He/She will report immediately to the BSO all violations of the policies and procedures and all significant research-related accidents (spills, needle-sticks, exposure, injuries, etc.) which result in overt or potential exposure to infectious materials, or their release into the environment, whether contained within the laboratory or not.
- He/She is prepared to implement methods for dealing with accident spills and personnel contamination.
- He/She has appropriate permits required by the United States Department of Agriculture (USDA), the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and any state or local permits for work with certain animal and plant pathogens are obtained prior to beginning work.
- He/She will follow all appropriate importation, exportation and interstate shipping requirements for certain biological materials. (Refer to Section 13.0 Packaging, Shipping, and Transportation).

Prior to beginning research, the PI shall:

- Receive appropriate approval for all research projects.
- Determine the usefulness of serological screening, the requirements of medical surveillance, and the availability of vaccination for Risk Group 2 and 3 agents. They shall inform the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested, such as vaccination or antibody titers. Where appropriate, the hepatitis B vaccination series should be offered *free of charge* to the employee. The PI is responsible for ensuring that records of HBV immunization and/or declination statements for his or her staff are kept on file with the PI.
- Submit BUA application for any protocol changes that modify the research procedures or alter the list of biohazards, upon which approval was originally based.
- Assure that personnel working with infectious agents or biohazardous materials are appropriately trained, have a complete understanding of the hazards involved, and are proficient in the practices and techniques required for the safe handling of such materials. Instruction in proper laboratory procedures and bloodborne pathogens training are available on UCR Learning Website.

During research, the PI shall:

- Appropriately supervise the performance of their staff to ensure that the required safety practices and techniques are employed.
- Investigate and report in writing to the IBC any significant biosafety problems pertaining to the pursuit of the research goals, specifically, new information which was not available at the time of the application. The PI is responsible for correcting any conditions that might expose their personnel or release of biohazardous materials into the environment.
- Implement the procedures prescribed for dealing with laboratory accidents.
- Assure that the biological characteristics of the microorganisms used in experiments haven't undergone adverse change. Periodic assessment should include the purity and phenotype of the strain. Special restrictive characteristics such as attenuation or replication deficiency require regular surveillance. Strain verification should be performed periodically on all replication-defective microorganisms.

Principal Investigators (PIs) who wish to perform research using biological materials should submit a Biological Use Authorization (BUA) application to the IBC for approval prior to beginning work. BUA applications should be submitted at least three weeks before the scheduled meeting and have adequately addressed any issues raised during the pre-review. The IBC generally reviews applications that involve work at Biosafety Level (BSL) 2 or 3, and the BSO and IBC Chair review Biosafety Level 1 (BSL-1) research applications. BSL-1 applications are approved *en masse* at a convened IBC meeting pending a positive review by the BSO and/or Chair. Exempt work involving recombinant or synthetic nucleic acid molecules under Section III-F of the NIH Guidelines requires IBC registration for verification by the BSO as other federal and state standards of biosafety may still apply to the research. Review and approval by the IBC is not required. IBC review includes an independent assessment of the containment levels required by the NIH Guidelines for the proposed research, an assessment of the laboratory facilities, procedures and practices, and a review of the training and expertise personnel. For additional information on BUAs, refer to Section 4.0 Biological Use Authorization (BUA).

LABORATORY PERSONNEL

Laboratory staff, students and postdoctoral fellows who work in the laboratory should be responsible for the following:

- Familiarize and follow all protocols and organisms used in the laboratory regardless of whether or not they work directly with them.

- Know all emergency procedures established by the Principal Investigator (PI).
- Complete all appropriate training and verify documentation of training.
- Follow all appropriate laboratory practices as outlined in this manual.

3.0 RULES, REGULATIONS & GUIDELINES

The following is a brief summary of regulatory authorities that regulate or established guidelines for the use of biological materials, infectious agents and recombinant DNA molecules. Copies are available from EH&S.

BMBL, 5th Edition

The Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th edition, is the code of practice for biosafety – the discipline addressing the safe handling and containment of infectious microorganisms and hazardous biological materials.

www.cdc.gov/biosafety/publications/bmb15/BMBL.pdf

Medical Waste Management Act 2016

The Medical Waste Management Act governs the proper handling, storage, transport, treatment, and disposal of all medical waste.

<https://www.cdph.ca.gov/certlic/medicalwaste/Documents/MedicalWaste/2013/MWMAfinalJan2016.pdf>

NIH Guidelines

The National Institutes of Health (NIH) developed the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* to articulate safety practices and containment procedures for basic research involving recombinant or synthetic nucleic acid molecules, including the creation and use of organisms and viruses containing recombinant or synthetic acid molecules.

http://osp.od.nih.gov/sites/default/files/resources/NIH_Guidelines.pdf

4.0 BIOLOGICAL USE AUTHORIZATION (BUA) APPLICATION

The following information describes the requirements for research involving biohazardous materials.

Registration for the Use of Biological Materials

All Principal Investigators (PIs) planning to carry out research which may involve biohazardous materials should complete and submit a new Biological Use Authorization (BUA), and obtain approval from the UCR Institutional Biosafety Committee (IBC) prior to commencing research.

The BUA application is available electronically at Research and Economic Development portal (<https://research.ucr.edu/OrPortal/index.aspx>).

An approved BUA will:

- Describe the scope of work to be conducted with biohazardous materials
- Establish the biosafety level of containment
- Identify the researchers, lab workers and collaborators
- Authorize the PI to conduct the work
- Identify the approved work locations
- Specify the safe work practices and procedures that should be adhered to

PIs whose research comes under the governance of any of the following campus rules or governmental regulations are required to complete a BUA, and where applicable, maintain a medical surveillance program for laboratory employees.

- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
- Cal/OSHA Bloodborne Pathogens Standard
- Cal/OSHA Aerosol Transmissible Diseases Standard
- Medical Waste Management Act
- International, Federal, and State Transport, Import, or Export Regulations

Apply for a BUA

Use the BUA application system to apply for a new BUA, to amend or renew an existing authorization. Access the system via the Research and Economic Development Portal (<https://research.ucr.edu/OrPortal/index.aspx>) – hereinafter known as “Portal”.

BUA submission is required if working with the following:

- Recombinant DNA materials or technology
- Human source material (including established or primary cell lines, blood, body fluids, organs, and tissues)

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- Infectious agents (including Risk Group 1 agents that are infectious to vertebrates other than humans)
 - Toxins of biological origin
 - Transgenic plants or animals in which the genome will be altered by stable introduction of recombinant DNA into the germ-line (e.g. making founder lines and breeding existing lines to create new genetic lines, but NOT including purchasing or maintaining already established lines)
 - Human gene transfer
 - Wild caught animals
 - Primates or their source materials
 - Exotic or infectious arthropods and/or insects

A. First-time Applicants

To start a new BUA application, PIs will need to log into the Portal (<https://research.ucr.edu/OrPortal/index.aspx>) using his/her UCR NetID and password. Under the “Forms” tab, select “New BUA” and follow all directions to complete application.

B. Renewals

PIs are responsible for maintaining their BUA current at all times. BUAs should be renewed every three years, with the exception of BUAs covering work conducted at Biosafety Level 3, which are renewed annually. Courtesy renewal reminder notices are sent approximately 90 days prior to the expiration date of each application. If the PI does not respond within the prescribed period, the PI will be notified to cease the work, and EH&S and ORI will coordinate with the PI to complete all corrective actions required to obtain IBC approval.

To renew your BUA, log into the Portal using UCR Net ID and password. Under “Forms” tab, select “Renewal or Amendment.” After verifying understanding of instructions, select “Application to Renew or Modify an existing BUA”. Update all certifications and information, and be sure to “Submit to ORI” when completed.

C. Modifications/Amendments

It is important that the IBC and EH&S maintain accurate records of all ongoing experiments utilizing biological materials. Therefore, PIs should submit a modification/amendment request for changes in research locations, biomaterials, and/or experimental procedures which may impact the biosafety requirements. The modification should include a narrative describing proposed changes when adding biomaterials or procedures.

To submit a modification/amendment, follow the steps as mentioned in the above section under “Renewals.”

D. Termination

If a PI terminates a BUA, EH&S and the IBC should be notified. This notification will ensure that research specified in the BUA is no longer being conducted and that items which are no longer to be used are appropriately decontaminated and/or disposed.

BUA Violations

Violations, such as lapse in IBC approval, failure to obtain IBC approval, or performing work not covered in an approved BUA will require the PI to stop the work subject to IBC oversight. EH&S and ORI will notify the PI, departmental heads (chair and/or dean) and the VC-RED that the work does not have IBC approval and cannot be conducted until approval is obtained.

5.0 INSPECTIONS

EH&S Inspections

EH&S conducts both scheduled and unannounced inspections of laboratories on a regular basis. Inspections are not limited to biosafety, but rather encompass additional research-related categories such as chemical, fire and life, radiation, and general safety.

For biological safety, a typical inspection of a BSL1 or BSL2 laboratory will include, but may not be limited to, evaluation of the following items for compliance and/or accuracy:

Administration

-
- PI name and contact information, department, research locations
 - BUA approval number(s) posted/available
 - Biohazardous material(s), use locations, and biosafety levels listed on BUA
 - Emergency procedures and phone numbers posted
 - Active personnel listed on BUA

Equipment

- Biosafety cabinet annual certification and work practices
- Autoclave issues
- Eyewash present and inspected (for BSL2 facilities)
- Proper use of laboratory equipment (biosafety cabinets, centrifuges, sonicators, cell sorters, etc.) with bioagents

Labeling

- Biohazard labels present at the entrance to the laboratory, on equipment, and waste containers

Personnel Exposure Control

- Use of appropriate Personal Protective Equipment (PPE)
- Adherence to applicable medical surveillance program(s)
- Safety practices followed for aerosol-generating procedures
- Decontamination of work areas

Personnel Training

- Biosafety Training
- Bloodborne Pathogens Training (if needed)
- Hazardous Waste Management
- Laboratory Safety Orientation (Fundamentals) 2013
- Lab-specific Training

Waste Handling

- Proper disposal of dry and liquid biohazardous waste
- Decontamination procedures followed

- Autoclave certified for medical waste decontamination

Use of Sharps

- Sharps storage
- Sharps Disposal

Select Agents (when applicable)

- Security maintained
- Usage logs maintained
- Facility maintained

Regulatory Agency Inspections

Notify EH&S immediately upon receipt of an inspection notice from any regulatory agency. For your protection, EH&S should be involved and participate in all lab inspections.

6.0 RISK GROUPS

Infectious agents are categorized in risk groups based on their relative risk. Risk group classifications take into consideration the pathogenicity of the organism, mode of transmission and host range, availability of effective preventive measures (e.g. vaccines), and availability of effective treatment (e.g. antibiotics). There are four risk group classifications.

Risk Group	Basis for Classification
1	<ul style="list-style-type: none"> • Agents do not cause disease in healthy adult humans
2	<ul style="list-style-type: none"> • Agents cause disease but rarely serious • Vaccines or treatment usually available • Infection generally not by inhalation.
3	<ul style="list-style-type: none"> • Agents cause serious or lethal human disease • Vaccines or treatment may be available • Infection <i>usually</i> via inhalation
4	<ul style="list-style-type: none"> • Agents cause serious or lethal human disease • Vaccines or treatment <i>not usually</i> available

7.0 BIOSAFETY LEVELS

There are four biosafety levels that consist of combinations of laboratory safety practice and techniques, safety equipment and laboratory facilities. Each combination is specifically appropriate for the operations performed, for the documented or suspected routes of transmission of the infectious agents, and for the laboratory function or activity. The

recommended biosafety level for an organism represents the conditions under which the agents can be ordinarily handled safely. Biosafety levels are not equivalent to risk groups. Risk groups aid in determining which biosafety level to apply to the work being performed on a microorganism.

Standard Microbiology Practices	BSL 1	BSL 2	BSL 2+	BSL 3
The laboratory supervisor enforces policy that controls access to the laboratory.	Yes	Yes	Yes	Yes
Laboratory personnel should wash their hands after handling cultures, removing gloves and before leaving the laboratory.	Yes	Yes	Yes	Yes
Eating, drinking, smoking, handling contacts lenses, application of cosmetics, and storing food or beverage for human consumption are prohibited.	Yes	Yes	Yes	Yes
Pipetting by mouth is prohibited.	Yes	Yes	Yes	Yes
Policies for handling sharps such as needles, blades, pipettes, and broken glass are implemented. Use of sharps is reduced as much as possible.	Yes	Yes	Yes	Yes
<ul style="list-style-type: none"> • Needles should not be bent, cut, removed from disposable syringes, or otherwise manipulated. 	Yes	Yes	Yes	Yes
<ul style="list-style-type: none"> • Disposable sharps should be placed in specially designed puncture and leak-proof sharps containers and disposed of appropriately as medical waste. 	Yes	Yes	Yes	Yes
<ul style="list-style-type: none"> • Non-disposable sharps should be placed in a hard-walled container for transport to decontamination, preferably by autoclaving. 	Yes	Yes	Yes	Yes
<ul style="list-style-type: none"> • Broken glass should never be handled directly. Use tongs, forceps, or dustpan and brush. Use plastic instead of glass whenever possible. 	Yes	Yes	Yes	Yes
All laboratory procedures should be performed to minimize the creation of aerosols or splashes.	Yes	Yes	Yes	Yes
Decontaminate all work surfaces after completing work, or after splashes or spills.	Yes	Yes	Yes	Yes
Decontaminate all potentially biohazardous materials before disposal by an effective means.	Yes	Yes	Yes	Yes
<ul style="list-style-type: none"> • If decontamination of materials occurs outside the immediate laboratory, materials to be decontaminated should be transported in durable, leak proof containers that are secured prior to transport. 	Yes	Yes	Yes	Yes
<ul style="list-style-type: none"> • If decontamination occurs outside the facility, materials being transported should be packed in accordance with all applicable, local, state, and federal regulations. 	Yes	Yes	Yes	Yes
Signage incorporating the biohazard symbol should be posted when infectious agents are present.	Yes	Yes	Yes	Yes
<ul style="list-style-type: none"> • The sign may include the name of the agent(s), supervisor contact information, and other information such as PPE. 	Yes	Yes	Yes	Yes
<ul style="list-style-type: none"> • ANIMAL USE: The laboratory supervisor should post safety procedures and equipment required for entry into animal housing areas containing known or potentially infected animals. 	Yes	Yes	Yes	Yes
An effective integrated pest management program is required.	Yes	Yes	Yes	Yes
The laboratory supervisor should ensure that all laboratory personnel receive:	Yes	Yes	Yes	Yes

<ul style="list-style-type: none"> • Training appropriate to their duties • Training on how to take appropriate precautions • Training on exposure evaluation procedures • Annual updated training • Training whenever a new hazardous material or procedure is introduced • Information regarding the effect of the hazards in the laboratory on those with compromised immune competence. Specifically address the possible adverse effects of potential immunizations, prophylactic interventions, and potential hazards to women of childbearing age. Those who may be at increased risk for infection should be encouraged to self-identify to the institution's health care provider for counseling and guidance. 				
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Special Practices	BSL 1	BSL 2	BSL 2+	BSL 3
All persons entering the laboratory should be advised of the potential hazards and should meet specific entry and exit requirements.	No	Yes	Yes	Yes
Laboratory personnel are provided with medical surveillance and offered immunizations for agents handled or potentially present in the laboratory.	No	Yes	Yes	Yes
The institution establishes a policy regarding the collection and storage of serum samples from at-risk personnel.	No	Yes	Yes	Yes
The campuswide biosafety manual should be available and accessible.	Yes	Yes	Yes	Yes
The supervisor should ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with agents.	No	Yes	Yes	Yes
Potentially infectious materials should be in durable leak proof containers during collection, handling, processing, storage or transport within a facility.	No	Yes	Yes	Yes
Laboratory equipment should be routinely decontaminated as well as after any potential contamination.	No	Yes	Yes	Yes
<ul style="list-style-type: none"> • Spills should be contained, decontaminated and cleaned up by personnel trained to work with infectious material 	No	Yes	Yes	Yes
<ul style="list-style-type: none"> • Equipment should be decontaminated before repair, maintenance, or removal from the laboratory. 	No	Yes	Yes	Yes
Potential infectious agent exposure incidents are immediately evaluated and treated per the laboratory biosafety manual. They are reported to the supervisor. Medical evaluation, treatment and surveillance are provided as appropriate.	No	Yes	Yes	Yes
Animals and plants not involved in the experiment are not permitted in laboratory.	No	Yes	Yes	Yes
All laboratory procedures that may generate aerosols should be performed in a properly certified biological safety cabinet or other physical containment device.	No	Yes	Yes	Yes
<ul style="list-style-type: none"> • Centrifugation of potentially infectious material requires the use of safety cups if the centrifuge is outside of a biosafety cabinet. 	No	Yes	Yes	Yes
<ul style="list-style-type: none"> • Sonication of potentially infectious material requires the use of a biosafety cabinet or sealed cup horn. 	No	Yes	Yes	Yes

ANIMAL USE: Animal caging is washed prior to re-use.	No	Yes	Yes	Yes
<ul style="list-style-type: none"> Animal caging should be sterilized before removal from laboratory and prior to washing. 	No	Yes	Yes	Yes

Safety Equipment (Primary Barriers and PPE)	BSL 1	BSL 2	BSL 2+	BSL 3
Primary barriers such as biosafety cabinets should be used when handling biohazardous materials. This may include pipetting, grinding, centrifuging, shaking, blending, sonicating, opening containers of infectious material, intranasal animal inoculation, harvesting infected tissues from animals or eggs, or if high concentrations are used.	No	Yes	Yes	Yes
<ul style="list-style-type: none"> Biosafety cabinets should be certified at least annually, and whenever moved or after repair work is done, if used to contain biohazards. 	Yes	Yes	Yes	Yes
<ul style="list-style-type: none"> Biosafety cabinets are installed so that laboratory air movement does not disrupt cabinet operation; away from doors, windows, high-traffic areas, ventilation registers and other disruptions. 	No	Yes	Yes	Yes
<ul style="list-style-type: none"> HEPA-filtered cabinet exhaust may be re-circulated to the laboratory if the cabinet is certified at least annually. The exhaust may also be ducted to the outside via either a thimble- or hard-connected exhaust duct. 	No	Yes	Yes	Yes
ANIMAL USE: Eye, face and respiratory protection may be required in rooms housing infected animals, as determined by risk assessment.	No	Yes	Yes	Yes
Laboratory coats, gowns or uniforms are required to protect personal clothing. They are removed when leaving laboratory areas, and are not worn to non-laboratory areas. They are not taken home for laundering, but are laundered or disposed of by the institution.	Yes	Yes	Yes	Yes
<ul style="list-style-type: none"> Solid front gowns, scrub suits or coveralls are required instead of lab coats. Reusable PPE should be decontaminated before laundering. 	No	No	Yes	Yes
Personnel should wear goggles or face shields if splashes or aerosols of hazardous materials may occur.	Yes	Yes	Yes	Yes
<ul style="list-style-type: none"> Eye protection PPE should be disposed of with other contaminated waste or decontaminated before reuse. Contact lens wearers should also use eye protection. 	No	Yes	Yes	Yes
Gloves should be worn when handling hazardous materials. Glove material should be chosen based upon the nature of the hazardous material. Alternatives to latex should be provided. Wash hands before leaving the laboratory.	Yes	Yes	Yes	Yes
<ul style="list-style-type: none"> Change gloves whenever they are contaminated, have been penetrated or damaged, or when otherwise appropriate. 	Yes	Yes	Yes	Yes
<ul style="list-style-type: none"> Remove gloves and wash hands when work with hazardous materials is finished, and before leaving the laboratory. 	Yes	Yes	Yes	Yes
<ul style="list-style-type: none"> Do not re-use or wash disposable gloves. 	Yes	Yes	Yes	Yes
<ul style="list-style-type: none"> Appropriate hand washing protocols should be rigorously followed at all times. 	Yes	Yes	Yes	Yes
<ul style="list-style-type: none"> Double gloving may be appropriate. Recommend using darker color inner glove and lighter color outer glove to more easily identify breaks or tears in an outer glove. 	No	Yes	Yes	Yes

<ul style="list-style-type: none"> • Inner gloves may have long gauntlets to cover gown sleeve cuff. 	No	No	Yes	Yes
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Based upon CDC’s BMBL, 5th Edition.

8.0 ANIMAL BIOSAFETY

Animal research is highly regulated, and UCR is committed to fully comply with all regulatory agencies and oversight groups. All research experiments involving animals at UCR should be reviewed and approved by UCR Institutional Animal Care and Use Committee (IACUC). Researchers are required to submit an Animal Use Protocol (AUP) and comply with the Campus Veterinarian requirements.

In addition to the required IACUC approval, an approved Biological Use Authorization (BUA) is required to work with animals involving the use of rDNA (including generation of, but not the purchase of transgenic animals) and/or infectious or transmissible agents. Applicants should fill in the “Vertebrates” section of the BUA application. The following information needs to be described in the application:

- Work involving animals
- Any hazards that UCR Vivarium staff may be exposed to
- How applicants will ensure that vivarium staff are protected

Animal biosafety containment level is assigned by the Institutional Biosafety Committee (IBC) for each BUA involving animal use. For Animal Biosafety Level Criteria (ABSL 1-4), refer to CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition.

For proper disposal of animal carcasses, refer to Section 18.0 Waste Management of this manual.

For more information about the IACUC, visit <http://research.ucr.edu/ori/committees/iacuc.aspx>

9.0 LABORATORY DESIGN

Laboratories designed for the intent of biological material use should follow CDC's BMBL, 5th Edition as described below.

Laboratory Facilities (Secondary Barriers)	BSL 1	BSL 2	BSL 2+	BSL 3
Laboratories should have doors to isolate them from non-laboratory areas.	Yes	Yes	Yes	Yes
Laboratories should be separated from unrestricted traffic within the building.	No	No	Yes	Yes
<ul style="list-style-type: none"> Doors should be self-closing, have locks, and be kept locked as described by institutional policy 	No	Yes	Yes	Yes
<ul style="list-style-type: none"> Laboratory access is through a two door passage, which may contain an anteroom and airlock system 	No	No	Yes	Yes
<ul style="list-style-type: none"> ANIMAL USE: doors should be kept closed when experimental animals are present. 	Yes	Yes	Yes	Yes
Laboratories should be kept neat; good housekeeping procedures should be in place and in regular use.	Yes	Yes	Yes	Yes
Laboratories should have a sink for hand washing.	Yes	Yes	Yes	Yes
<ul style="list-style-type: none"> The sink should be located near the laboratory exit. It may be manually, hands-free or automatically operated. 	Yes	Yes	Yes	Yes
<ul style="list-style-type: none"> The sink should be operated hands-free or automatically. 	No	Rec	Yes	Yes
<ul style="list-style-type: none"> If the laboratory is separated into zones, each zone should have its own sink. 	No	No	Yes	Yes
Laboratory furniture should be secured and appropriate for anticipated loads and uses. Spaces between benches, cabinets, and equipment should be accessible for cleaning and decontamination.	Yes	Yes	Yes	Yes
<ul style="list-style-type: none"> Bench tops are impervious to water, moderate heat and chemicals. 	Yes	Yes	Yes	Yes
<ul style="list-style-type: none"> Laboratories are designed for ease of decontamination (e.g. no carpets, sealed surfaces, no unreachable areas, etc.) 	Yes	Yes	Yes	Yes
<ul style="list-style-type: none"> Floors should be slip resistant and impervious to liquids and chemicals. Seamless floors with integral covered bases are strongly recommended. 	No	No	Yes	Yes
<ul style="list-style-type: none"> Walls should be constructed with a smooth sealed finish, resistant to water and chemicals. All penetrations should be sealed to prevent contamination of adjacent air spaces. 	No	No	Yes	Yes
<ul style="list-style-type: none"> Ceilings should be constructed following the same criteria for walls. 	No	No	Yes	Yes
<ul style="list-style-type: none"> Seating in the laboratory should be covered with a non-porous material that can easily be cleaned and decontaminated. 	Yes	Yes	Yes	Yes
All laboratory windows to the outside should be fitted with fly screens.	Yes	Yes	NA	NA
<ul style="list-style-type: none"> Windows to the outside should be avoided, but if present should be permanently sealed. 	No	No	Yes	Yes
Vacuum lines should be protected by HEPA filters that are cleaned or replaced as needed. Filter traps may be required.	No	Yes	Yes	Yes
Autoclave, chemical disinfection, incineration or other approved decontamination method should be available in the facility for waste treatment prior to disposal.	No	Yes	Yes	Yes

No material or equipment can leave the laboratory unless it is autoclaved or otherwise decontaminated, or is properly packed for shipment, or is encapsulated by an approved vendor for off-site decontamination.	No	No	Yes	Yes
Laboratory design and operation should allow the entire laboratory to be decontaminated in case of gross contamination, major renovation, or maintenance shutdowns.	No	No	Yes	Yes
Laboratory design should allow for the decontamination of large pieces of equipment prior to removal from the laboratory (decontamination airlock).	No	No	Yes	Yes
A ducted ventilation system for the laboratory is required.	No	Rec	Yes	Yes
<ul style="list-style-type: none"> Pressure differentials between rooms should be maintained such that air is drawn from clean to contaminated areas. System design should prevent reversing this differential. 	No	No	Yes	Yes
<ul style="list-style-type: none"> Laboratory personnel should be able to visually confirm directional airflow. Consideration should be given to quantitative monitors and audible alarms in case of ventilation failure. 	No	No	Yes	Yes
<ul style="list-style-type: none"> Exhaust from the laboratory ventilation system should not re-circulate to any other part of the building. 	No	No	Yes	Yes
<ul style="list-style-type: none"> Exhaust from the laboratory should be dispersed well away from occupied areas, or the exhaust should be HEPA-filtered. 	No	No	Yes	Yes
<ul style="list-style-type: none"> Sufficient supply air should be provided to the laboratory at all times to ensure that biosafety cabinet airflow is not compromised. 	No	No	Yes	Yes

Rec = recommended but not required

Laboratory designs also need to follow the [UC EH&S Laboratory Safety Design Guide \(http://ehs.ucr.edu/forms/laboratorysafetydesign.pdf\)](http://ehs.ucr.edu/forms/laboratorysafetydesign.pdf).

10.0 CONTAINMENT

BIOSAFETY CABINETS

Biosafety Cabinet Characteristics Comparison

Biological Safety Cabinets (BSCs) are designed to provide personnel, environmental and product protection when appropriate practices and procedures are followed. Three kinds of BSCs, designed as Class I, II and III, have been developed to meet varying research needs. Selection of a Biosafety Cabinet through Risk Assessment (adapted from BMBL 5th Ed).

Biological Risk Assessed	Protection Provided			BSC Class
	Personnel	Product	Environmental	
BSL 1 – 3	Yes	No	Yes	I
BSL 1 – 3	Yes	Yes	Yes	II (A1, A2, B1, B2)
BSL – 4	Yes	Yes	Yes	III; II – When used in suit room with suit

Comparison of Biosafety Cabinets Characteristics (adapted from BMBL 5th Ed)

BSC Class	Face Velocity	Airflow Pattern	Applications	
			Nonvolatile Toxic Chemicals and Radionuclides	Volatile Toxic Chemicals and Radionuclides
I	75	In at front through HEPA to the outside or into the room through HEPA	Yes	When exhausted outdoors
II, A1	75	70% recirculated to the cabinet work area through HEPA; 30% balance can be exhausted through HEPA back into the room or to outside through a canopy unit	Yes (minute amounts)	No
II, B1	100	30% recirculated, 70% exhausted. Exhaust cabinet air should pass through a dedicated duct to the outside through a HEPA filter	Yes	Yes (minute amounts)
I, B2	100	No recirculation; total exhaust to the outside through a HEPA filter	Yes	Yes (small amounts)
II, A2	100	Similar to II, A1, but has 100 lfm intake air velocity and plenums are under negative pressure to room; exhaust air can be ducted to the outside through a canopy unit	Yes	When exhausted outdoors (minute amounts)
III	N/A	Supply air is HEPA filtered. Exhaust air passes through two HEPA filters in series and is exhausted to the outside via a hard connection	Yes	Yes (small amounts)

How to Properly Use a Biosafety Cabinet

Before Use:

1. Wear appropriate PPE.
2. Check certification sticker located on the exterior surface of BSC to confirm that BSC has been certified within the past 12 months. Notify PI if BSC certification exceeds 12 months. In this case, do not use BSC.
3. Turn on cabinet blowers for at least 5 – 10 minutes prior to beginning work.
4. Check the gauge to ensure BSC is working properly.
5. Turn on the light in the BSC.
6. Raise the sash to the operating level and ensure that the height is comfortable for cleaning. Silence the alarm if it is activated.
7. Adjust seat height so that researcher's face is above the front opening.
8. Using a squeeze bottle, spray the appropriate disinfectant onto interior surfaces of the BSC (work surface, side walls, back walls, front grill, inner glass of sash etc).
9. Wipe down the work surface area by starting at the left front corner at the grill and wiping across the front grill. Continue wiping horizontally across towards the back of the BSC (see Figure 1 – yellow arrows).
10. Wipe down inner glass of sash by starting on the lower left corner and wiping up and down while moving horizontally (see Figure 1 – blue arrows).



Figure 1. Cleaning work surface (yellow arrows) and sash (blue arrows)

11. Wipe down side walls and back of BSC (see Figure 2).

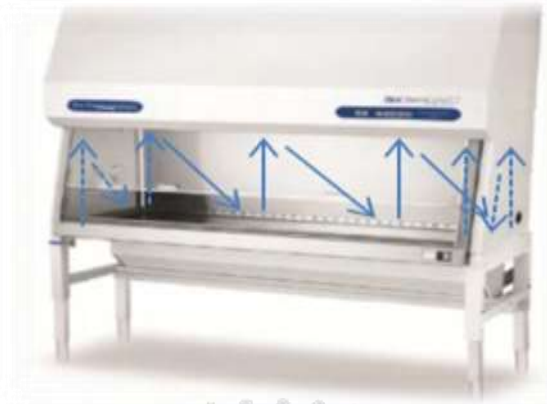


Figure 2. Cleaning side walls and back

12. With soiled paper towels in hand, remove outer gloves and dispose into biohazard bag.
13. Replace outer gloves. BSC is ready to be set up before commencing work.
14. Set up BSC to reduce potential for contamination. Place all materials as far back in the cabinet as practical, away from the front grill. Set up BSC work flow from clean to dirty.
15. Attach an in-line HEPA filter to aspiration suction flask. Ensure the aspiration suction flask contains appropriate disinfectant (see Figure 3) and is stored in a secondary container.

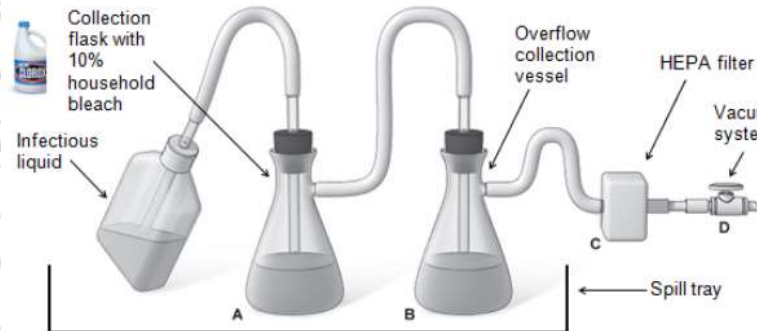


Figure 3. Aspiration flask set up

CENTRIFUGE SAFETY

Centrifuges cause serious hazard concerns due to the possibility of mechanical failure and the creation of aerosols. Follow the following guidelines to minimize the risk of mechanical failure and aerosol hazards.

To Avoid Mechanical Failure:

- Follow manufacturer instructions to avoid metal fatigue, distortion, or corrosion.

-
- Review the operating manual before using a centrifuge.
 - Maintain and operate the centrifuge according to manufacturer instructions.
 - Examine the centrifuge often for damage or poor maintenance.
 - Properly train users. Post operating instructions that include safety precautions on the unit.
 - Contact vendor in case of any problems.

To Avoid Rotor Failure:

High-speed rotor heads are at risk to metal fatigue. Failure to discard rotors after a predetermined amount of use can result in dangerous and expensive rotor disintegration. **It is extremely important to avoid rotor failure.** Follow these guidelines to reduce the risk of rotor failure:

- Use appropriate rotor with the appropriate centrifuge.
- Use sealed rotors, sealed buckets, or a guard bowl with a gasket and cover, as well as safety centrifuge tubes (tube or bottle carrier with sealable cap or “O” gasketed cap).
- Read operating manual for each machine before using the equipment.
- Follow manufacturer specifications for the rotors and tubes. Keep manual near the unit for easy reference.
- Follow the manufacturer’s maximum speed and sample density ratings designations to prevent stress failures.
- Keep track of each rotor, recording the purchase date of each rotor, manufacturing date, serial number, the length of time and speed for each use.
- Discard rotors according to the manufacturer’s recommended schedule.

Minimizing Aerosols:

Aerosols are fine particles of liquid droplets produced when energy is applied to a liquid, and such liquid escapes into the environment. Aerosols are potentially created during the process of centrifugation, filling centrifuge tubes, removing plugs or caps from tubes after centrifugation, and/or removing supernatant resuspending sedimented pellets. The highest concern for aerosol hazards include a tube breaking during centrifugation.

Follow these guidelines to minimize aerosols when centrifuging biohazardous materials:

- Fill and open centrifuge tubes, rotors, and accessories in a biosafety cabinet (BSC).

- Use sealed tubes and safety tubes with O-rings. Inspect O-rings and buckets before each use.
- Do not use aluminum foil to cap centrifuge tubes.
- Avoid overfilling centrifuge tubes to prevent caps from becoming wet.
- After tubes are filled and sealed, wipe the exterior of the tube with disinfectant.
- Add disinfectant to the space between the tube and the bucket to disinfect material in the event of breakage during centrifugation.
- Properly balance buckets, tubes, and rotors before centrifugation.
- Open centrifuge tubes that contain biohazardous materials 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 HEPA filter.

11.0 HAZARD COMMUNICATION

UCR is committed to ensuring that all employees are made aware of the current regulations, and processes are in place to comply with the regulations. UCR is also committed to keeping employees informed of possible biohazards in their work areas and of procedures to prevent and control exposure to bloodborne pathogens, other potentially infectious material (OPIM), or aerosol transmissible pathogens-laboratory (ATPs-L). Employees/Laboratory personnel are informed of the standard regulations, work-related biohazards, and the Exposure Control Plan through a combination of training programs, distributed written materials, and the use of applicable alert labels and signs within the work area itself.

12.0 LABELS AND SIGNS

Warning labels should be securely affixed to containers of biohazardous materials, medical and regulated wastes, refrigerators and freezers containing blood, other potentially infectious material (OPIM), or aerosol transmissible pathogen – laboratory (ATP-L), and other containers used to store, transport, or ship blood, OPIM, or ATP-L.

The warning labels used should list the word “Biohazard” and display the international biohazard symbol. The labels are fluorescent orange and/or red with contrasting letters/symbols (see below).



Example 1



Example 2

Biohazard warning signs should be posted at the entrance of any restricted areas where certain biohazardous materials are used. The hazard warning sign should include the biohazard symbol, category name of the agent(s), special entry requirements and 24-hour contact information for two responsible individuals, one of whom should be the Principal Investigator (PI).

Detailed information regarding laboratory-specified biohazard issues are found in the Principal Investigator's BUA.

Contaminated equipment should also be labeled with the "Biohazard" label. Additionally, the label should state which portions of the equipment remain contaminated.

13.0 PACKAGING, SHIPPING, AND TRANSPORTATION

Packaging, Shipping, and Transportation

Federal (Department of Transportation, 49 CFR §171-175) and international agencies (IATA – International Air Transport Association) have in place numerous regulations for shipping of dangerous goods by surface or air.

Any person involved in packaging, handling, shipping or transporting hazardous materials should receive training in the general requirements of handling hazardous materials as well as function specific training for the specific task(s) performed. Training is required before performing any tasks associated with shipping hazardous materials and periodically thereafter.

Transportation Outside of the Laboratory:

- Biohazardous agents should be properly handled, contained and labeled to transport between locations to prevent accidental exposure to unsuspecting persons outside of the laboratory.
- Biohazardous agents should be placed in securely closed primary containers. The exterior of the primary container should be decontaminated prior to transportation.
- The primary container should be placed in a covered, leak proof, shatterproof secondary container. The secondary container should be labeled with the biohazard symbol, the biohazardous agents present and the lab of origin. If it is transported by vehicle, the name and telephone number of the PI or other responsible person(s) should be included on the outside of the secondary container.

Shipment Off-Campus (Domestic Shipment):

- Three federal regulatory agencies specify requirements for packaging and shipping of biological materials. The United Nations publishes recommendations for packing and shipping biological materials, and both the International Civil Aeronautics Organization and International Air Transport Association (IATA) publish regulations based on the UN's recommendations. The requirements for all these regulations are similar; therefore, most carriers elect to follow the IATA regulations set forth in their Dangerous Goods Regulations (DGR).

When transporting infectious agents, the shipper is responsible for the proper packing of dangerous goods and should pack biological agents as infectious substances (Packing Instruction 602, IATA-DGR) or diagnostic specimens (Packing Instruction 650, IATA-DGR).

- It is important not to leave the package unattended.
- UCR Material Management's Receiving and Shipping are trained to safely ship, receive and transport any biological materials. The following are packing instructions for infectious substances:

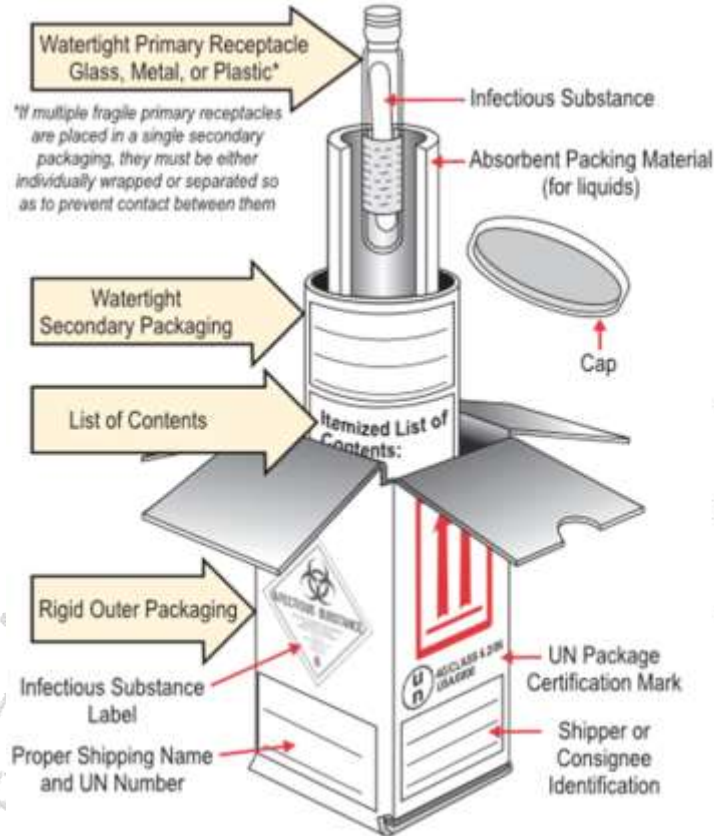


Image: U.S. Department of Transportation - Example of Proper Packaging

- Primary Container
 - The specimen will be placed in a securely closed, watertight primary container. Stoppers and screw-capped tubes will be secured with waterproof tape.
 - The contents of the primary containers will not exceed 50 ml.
 - The exterior of the primary container will be decontaminated prior to transportation.
 - A biohazard label will be placed on the exterior of the primary container. (For details on label, see Section 12 – Labels and Signs)
- Secondary Container
 - One (or more) primary container(s) may be placed within the secondary container as long as the total volume of the specimen does not exceed 50 ml.

- The absorbent material used within the secondary container should be sufficient to absorb the contents of the primary container(s), if it should leak.
 - The secondary container should be free of contamination and labeled with the same symbol as the primary container.
 - Outer Container
 - This container will be made of corrugated fiberboard, cardboard, wood or other material of equivalent strength.
 - The interior of the outer container may be filled with coolant material such as ice or dry ice. If ice or dry ice is used, additional shock absorbent material will be added and positioned in a manner that allows protection of the specimen should the ice or dry ice melt or sublimate. The dry ice should be placed outside of the secondary container in the outer container. An additional placard is required with the mass of dry ice indicated on the placard.
 - The exterior will be labeled with the special sticker as depicted below.
 - Prior to transport, the outer container should be sealed or secured in a manner as to make it leak-proof should the container be placed on its side.
 - The package will be decontaminated before shipment.

International Shipments:

All domestic and international shipments of infectious substances require the use of packaging that has been tested and certified to carry such material.

- The certified packaging will have United Nations performance markings on the outside indicating that it has met performance tests.
- A statement should be included in the additional handling information that states, “Prior arrangements as required by the IATA Dangerous Goods Regulations 1.3.3.1 have been made.”
- The shipper should include the name and telephone number of the person responsible for the shipment.
- Diagnostic specimens being shipped for the purpose of initial diagnosis are excluded from the regulations. However, diagnostic specimens known, or thought likely, to contain infectious substances are included.
- All shipments should go through UCR Material Management’s Receiving and Shipping.

Receipt of Packages:

- Upon receipt of any packaged specimens, immediately check for leakage or damage.
- If leaking:
 - Isolate the package either in a Class II biological safety cabinet or in a leak-proof, sealed container. Add disinfectant and dispose of as medical waste.
 - Call EH&S if Risk Group 3 agents are involved. Submerge contents in 10% bleach.
 - Keep unauthorized personnel away from the package.
- The package should be opened in the laboratory on an easily cleanable, water-resistant surface.

**NOTE: Work requiring BSL-3 level containment is not currently allowed to be conducted at UC Riverside.

14.0 DISINFECTING | DECONTAMINATION

Decontamination is the cleaning process that removes contaminants such as microorganisms or hazardous materials, including infectious diseases.

Methods

Heat Sterilization

Heat sterilization is achieved by using an autoclave, a piece of equipment with a chamber used to sterilize items by applying wet heat (i.e. high-pressure steam) at temperatures above the normal boiling point of water and pressures above normal atmospheric pressure. Autoclaves are used to sterilize laboratory equipment or materials such as glassware, media, reagents, or waste.

All autoclaves at UCR should be registered with the Biosafety program at EH&S. Autoclaves that sterilize biological waste should be registered with the Monthly Autoclave Testing Program. This program establishes a responsible party to conduct a monthly testing of the autoclaves using *Bacillus strearothermophilus*. An autoclave use log should be completed by each user for each autoclave cycle. Records should be kept for a minimum of three years.

Liquid Disinfection

Liquid disinfectant effectiveness varies with the organism, contact time, concentration, and other conditions of use. Liquid disinfectants should be used when they are confirmed to be effective against the organism(s) present. No liquid disinfectant is equally useful or effective under all conditions and for all viable agents.

Liquid disinfection is typically used for surface decontamination and, when used in sufficient concentration, as a decontaminant for liquid wastes prior to final disposal in the sanitary sewer.

Vapors and Gases

Vapors and gases are used in a closed systems and under controlled conditions of temperature and humidity. Agents in this category include the aerosol, vapor, or gas phase of chlorine dioxide, glutaraldehyde, paraformaldehyde, ethylene oxide, peracetic acid, and hydrogen peroxide.

Vapors and gases are primarily used to decontaminate biosafety cabinets, animal rooms, and their associated systems, bulky or stationary equipment not suited to liquid disinfectants, instruments or optics that might be damaged by other decontamination methods, and rooms, buildings, and associated air-handling systems.

Due to the hazardous nature, contact Biosafety Officer (951) 827- 5528 prior to administration.

15.0 SELECT AGENTS

Select Agents are materials that have been identified by the U.S. Government as agents that have potential use in biological terrorism or warfare. The National Select Agents Registry Program (NSAR) oversees the possession, transfer and use of select biological agents and toxins that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products in the United States and its territories. The NSAR requires government agencies, universities, research institutions, and commercial entities that possess, transfer, and use biological agents and toxins (see below “List of Select Agents) to register with the program and UCR IBC. The NSAR allows possession of nine select agents and toxins at “exempt quantities” (see below “Exempt Quantities of Select Agents) without registration with NSAR; however, UCR IBC review and approval is still required. Additional information can be accessed at <http://www.selectagents.gov/index.html>.

List of Select Agents

The most current list of select agents can be found here:

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

Exempt Quantities of Select Agents

Regulated toxins of biological origin (see table below) can be ordered, used, or maintained in the laboratory provided the total quantity per PI, for all areas under the PI’s control, does not exceed the limits posted in the table below. PIs are required to register with UCR IBC.

The most current list of “Maximum Allowable Quantities” can be found here: <http://www.selectagents.gov/PermissibleToxinAmounts.html>

HHS Toxins [§73.3(d)(3)]	Amount
Abrin	1000 mg
Botulinum neurotoxins	1 mg
Short, paralytic alpha conotoxins	100 mg
Diacetoxyscirpenol (DAS)	10,000 mg
Ricin	1000 mg
Saxitoxin	500 mg
Staphylococcal Enterotoxins (subtypes A, B, C, D and E)	100 mg
T-2 toxin	10,000 mg
Tetrodotoxin	500 mg

It is important to ensure that the total amount of toxin per PI in a laboratory is maintained below these limits at all times for exemption from registration and restrictive Select Agent requirements. **Failure to register a Select Agent is a criminal offense, punishable by up to five years in prison and/or \$500,000 in fines. (Public Health Security & Preparedness Response Act of 2002, s. 231(c)).**

Possession, Use, or Transfer of Select Agents

In order to possess, use, send or receive Select Agents in amounts equal to or greater than those listed at the NSAR for a given agent, an institution and each individual who will have access to the Select Agent(s) should first satisfy each of the following requirements:

- Register with U.S. governing bodies (CDC and/or APHIS) through UCR EH&S
- Official authorization granted for each individual requesting access to Select Agents provided by the U.S. Federal Bureau of Investigation, the applicable U.S. governing body, and UCR

Please note that violations of Select Agent rules and regulations can lead to severe criminal or civil penalties. Imprisonment and fines up to \$250,000 may be levied against individuals who are found to be in violation of these laws.

Registration of Possession, Use, or Transfer of Select Agents

All activity involving Select Agents should be registered with UCR EH&S prior to initiation. Please contact EH&S Biosafety at 951-827-5528 to initiate a registration for your proposed Select Agent activity.

The following summarizes the Select Agent registration and compliance process at UCR:

- Notify EH&S of your intent to possess, use or transfer Select Agents.
- Complete an update of the APHIS/CDC Form, Application for Registration: <http://www.selectagents.gov/Forms.html>
- Complete FBI [Form FD961](#) and file with UCR EH&S for registration with applicable federal entity.
- Complete 2 sets of FBI fingerprint cards for initiation of background investigation check.
- Complete EH&S applicable training programs.

- Satisfactory completion of EH&S laboratory inspection of proposed work practices, safety equipment, and facilities, to evaluate compliance with CDC/APHIS, and Select Agent regulatory requirements (Safety and Security).
- Receive final approval and authorization from EH&S, FBI, and the applicable governing body for you and each individual requesting access to Select Agents, for the proposed storage location, and research areas.

Your laboratory will be subject to EH&S and federal inspections or audits prior to initiation of work and at any time during your possession of Select Agents.

Discovery of Select Agents, Unknown Samples, or Missing Samples

Notify EH&S immediately if:

- You identify any Select Agent pathogen or toxin listed on the current federal list that was not previously registered by your lab
- You discover a toxin not previously reported by your laboratory in excess of the federal maximum allowable quantities listed above
- You discover any unknown materials in your laboratory for assistance with identification

These discoveries should be reported to the applicable governmental institution(s).

Intra-facility Transfer of Select Agents

Select Agent pathogens and toxins may not be transferred outside of, to, or within UCR unless EH&S and federal approval has been granted. An intra-facility transfer is defined as the transfer of a Select Agent from one EH&S and federally registered Select Agent lab to a similarly registered laboratory. Select Agents may not be transferred to a laboratory that is not registered with EH&S and the applicable governmental institution. Once approved, intra-facility transfers will be overseen by EH&S.

Destruction of Select Agents or Unknown Samples

Select Agent pathogens or toxins may not be destroyed until EH&S and the applicable government institution have provided approval for the destruction. Once approval has been granted for the destruction of Select Agents, EH&S will officially assume possession of the

material and record its destruction. The governing institution will alert UCR if witnesses are required.

If you have any questions regarding the UCR or Federal Select Agent process, please contact the EH&S Biosafety group at 951-827-5528.

16.0 SHARPS INJURY

Immediately clean the affected area with soap and water and notify your supervisor immediately of any sharps injury. Report all sharps injuries by completing the [UCR Incident and Investigation Report \(http://hr.ucr.edu/supervisor/reportincident.html\)](http://hr.ucr.edu/supervisor/reportincident.html) within one (1) business day and submit to Workers' Compensation and Environmental Health and Safety (EH&S). The Biosafety Officer (BSO) from the EH&S office will review the injury and enter the information into the Sharps Injury Log Form (Appendix A) within 14 days of the exposure. The BSO will maintain the Sharps Injury Log for five years from the date the exposure incident occurred.

17.0 SPILL PROCEDURES

In any spill scenario, the priority of actions is determined by the “PEP” rule – People, Environment, and Property. The highest priority is to provide aid to injured personnel and prevent spill area access to others. Next, action should be taken to prevent environmental damage if it can be done without endangering personnel. An example would be to prevent a potent toxin from entering a sanitary drain by placing an absorbent in the flow path. Finally, action to prevent property damage should be taken if it can be done safely.

Small spills involving most biological materials used at UCR may be handled by trained laboratory personnel. If a spill is large or if laboratory personnel are uncomfortable handling the spill on their own, contact the following:

EH&S	During business hours	(951) 827 – 5228
UCPD	Emergency	9-1-1
UCPD	Non-Emergency Non-Business Hours	(951) 827 – 5222

Laboratory personnel should be prepared to clean up small spills of biological or biohazardous material. Keep basic clean up equipment on hand and ensure that all laboratory staff are trained

to clean up spills. Researchers working with Risk Group 2 or 3 (RG2 or RG3) materials should prepare fresh 1:10 bleach solutions weekly for routine decontamination.

Biological Agents Spill within a Biosafety Cabinet:

1. Keep the biosafety cabinet on.
2. Don appropriate PPE for cleaning up the spill (gloves, lab coats, safety goggles, etc.).
3. Place absorbent materials on and around the spill (e.g. paper towels).
4. Apply an effective disinfectant (e.g. 1:10 dilution of bleach) to the spill and allow it to sit for the appropriate contact time (e.g. 15-30 minutes for bleach). Avoid splashing and creation of aerosols.
5. Clean/Wipe the spill area.
6. Dispose waste into red biohazard bag.
7. Clean the area again (if using bleach as a disinfectant, do a final wash of the area with 70% alcohol or water to prevent corrosion of your biosafety cabinet).
8. Remove PPE.
9. Wash hands.
10. Report the spill to your PI/Lab Manager/Supervisor.

Biological Agents Spill Outside of a Biosafety Cabinet (BSL-2 Laboratories):

1. Notify all personnel in the area that a spill has occurred and evacuate everyone in the vicinity.
2. Close the door.
3. Remove any contaminated clothing and wash exposed areas with mild soap and water for 15 minutes.
4. Report details and/or request assistance.

EH&S	During business hours	(951) 827 – 5228
UCPD	Emergency	9-1-1
UCPD	Non-Emergency Non-Business Hours	(951) 827 – 5222

5. Wait 30 minutes to allow aerosols to settle or vent.
6. Don appropriate PPE for cleaning up the spill (e.g. gloves, lab coat, safety goggles, and respirator (if spill involves the release of ATPs-L)).
7. Place absorbent materials on and around the spill (e.g. paper towels).

8. Apply an effective disinfectant (e.g. 1:10 dilution of bleach, 70% ethanol, etc.) to the spill and allow it to sit for the appropriate contact time (e.g. 15-30 minutes for bleach). Avoid splashing and creation of aerosols.
9. Clean/Wipe the spill area.
10. Dispose waste into red biohazard bag.
11. Clean the area again.
12. Remove PPE.
13. Wash hands.
14. Report the spill to your PI/Lab Manager/Supervisor.

18.0 WASTE MANAGEMENT

Research with biohazardous materials generate medical waste which cannot be discarded in regular trash. The California Medical Waste Management Act 2016 and UCR Medical Waste Permit requires anyone generating, treating, or storing medical waste to comply with the following procedures:

Biological Solid Waste:

1. Label a **red biohazard bag** with *building and room number* before filling it.
For research Plant and Soil waste only, clear bag with red biohazard symbol is permitted.
2. Place the waste in the red biohazard bag (**orange bags are illegal in California**). Do not place glass pipettes or anything that will puncture the plastic bag. Rigid objects such as transfer pipettes can be decontaminated by exposure to a 10% household bleach solution for at least 30 minutes.
3. Place **autoclave tape** on the bag to confirm autoclave attainment of adequate sterilization conditions.
4. Contaminated waste should be stored in a labeled, rigid, puncture-proof container with a tight-fitting lid and biohazard symbol on all visible sides and top.
5. To dispose waste after autoclaving, take the biohazard bag directly to the building dumpster or make special arrangements with building services.
6. All waste should be decontaminated and disposed within seven (7) days of generation if stored at a temperature above 0°C.
7. All waste should be disposed within 90 days if stored at or below 0 °C.

Liquid Waste:

For liquid biological waste, liquid waste (cultures, stocks, and other regulated liquid waste) should be decontaminated by a 10% final concentration household bleach solution for 15-30 minute minimum contact-time prior to disposal down the sink with copious amounts of running water.

Contaminated Sharps:

Immediately dispose contaminated sharps into a sharps container that is rigid, puncture resistant, leak-proof on the side and bottom, portable, and labeled with the International Biohazard Symbol. For proper removal of sharps container, submit a waste pickup request by logging in to Waste Accumulation Storage Tracking Electronic (WASTE: <https://ehs.ucop.edu/waste/#/>), and create a “Biological” tag type, or if your sharps are contaminated with hazardous chemicals, create a “Chemical” tag type using the existing profile for sharps contaminated with hazardous chemicals. Update the sharps container tag status in WASTE to “Ready for Pick Up” and EH&S will pick up the container.

Infected Plant Material:

Infected plant material should be disposed of in clear autoclavable bags. All infected plant waste should be autoclaved before disposal in regular trash.

Animal Carcasses:

At UCR, disposal of animal carcasses is handled through the Office of Campus Veterinarian (OCV). Animal carcasses should be double bagged in red biohazardous bags, transported in leak-proof containers, and held in the freezer located in the vivarium until the next scheduled pick up from an approved vendor under contract with UCR. Follow procedures specified by the OCV.

19.0 TRAINING

Training is available online via ucrllearning.ucr.edu. The online classes meet the regulatory requirements mandated by Cal/OSHA. These cover general health and safety issues, and do not replace requirements for supervisors to train or make certain employees are trained in the specific hazards of their workplace.

Required training:

- Biosafety Training
- Bloodborne Pathogen Training
- Hazardous Waste Management
- Laboratory Safety Orientation (Fundamentals) 2013
- Laboratory-Specific Training
- Safety Orientation



Appendix A



Sharps Injury Log

The following information, if known or reasonably available, is documented within 14 working days of the date on which each exposure incident was reported.

1. Date and time of the exposure incident:

2. Date of Exposure incident report: _____ Report written by: _____

3. Type and brand of sharp involved: _____

4. Description of exposure incident:

- Job Classification of exposed employee: _____
- Department or work area where the incident occurred: _____
- Procedure being performed by the exposed employee at the time of the incident: _____

• How the incident occurred: _____

• Body part(s) involved: _____

• Did the device involved have engineered sharps injury protection? Yes ___ No ___

• Was engineered sharps injury protection on the sharp involved? Yes ___ No ___

If Yes	If No
A. Was the protective mechanism activated at the time of the exposure incident? Yes ___ No ___ B. Did the injury occur before, during or after the mechanism was activated? ___ Before ___ During ___ After ___ NA Comments: _____ _____	A. Does the injured employee believe that a protective mechanism could have prevented the injury? Yes ___ No ___

- Does the exposed employee believe that any controls (e.g. engineering, administrative, or work practice) could have prevented the injury? Yes ___ No ___

Employee's opinion:

- Comments on the exposure incident (e.g. additional relevant factors involved):

- Employee interview summary:

Picture(s) of the sharp(s) involved (please attach if available).

Appendix B. DEFINITIONS

Autoclave:

An autoclave is a piece of equipment with a chamber used to sterilize items by applying wet heat (i.e. high-pressure steam) at temperatures above the normal boiling point of water and pressures above normal atmospheric pressure. Autoclaves are used to sterilize laboratory equipment or materials such as glassware, media, reagents, or waste.

Biohazard

Biohazards are infectious agents or hazardous biological materials that present a risk or potential risk to the health of humans, animals, or the environment. Biohazards also include toxins of biological origin, human-derived materials, recombinant DNA and any materials potentially containing infectious agents or biohazards.

Biohazardous Materials

Biohazardous materials include but are not limited to bacteria, brain tissue, fungi, human and primate cells, tissues and body fluids, parasites, prions, recombinant DNA, transgenic plants, animals and insects, and viruses as outlined in laws, regulations, or guidelines.

Biological Use Authorization

Biological Use Authorization (BUA) is an application that describes the research that involves working with materials that are infectious (or potentially infectious) to plants, animals, or humans (including replication-incompetent viral vectors).

Biosafety

Biosafety is defined as the discipline that addresses the safe handling and containment of infectious microorganisms to protect workers, the public, agriculture, and the environment from exposure to biological agents or materials that may cause disease or other detrimental effects in humans, plants, or animals.

Medical Waste

Medical waste is defined by the Medical Waste Management Act as:

- Any biohazardous, pathology, pharmaceutical, or trace chemotherapy waste
- All sharps and any biohazardous waste from research involving the treatment, diagnosis or immunization of humans or animals
- Waste generated in autopsy or necropsy
- Waste generated in research using human or animal pathogens

- Laboratory waste such as human or animal specimen cultures that are infected with pathogens that are also infectious to humans

Laboratory wastes from the production of bacteria, viruses, spores, discarded live and attenuated vaccines used in human health care or research

