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*Table of Contents*

Guidelines p. 1

Template p. 7

Resources p. 13

Biosafety

Standard Operating Procedure

Biohazardous Materials

Guidelines

Purpose

This Standard Operating Procedure (SOP) is means to ensure that specific activities with biohazardous materials are conducted in a safe manner. SOPs are required as a part of the Biological Use Authorization (BUA) for all laboratories at Biosafety Level 2 and above.

Responsibilities

#### Principal Investigator

Principal Investigator (PI) has the primary responsibility for ensuring that his/her laboratory is safe by conducting an initial risk assessment, developing administrative controls, and ensuring that all work is conducted with the appropriate engineering controls. PI’s should refer to the applicable guidelines and regulations (e.g., National Institute of Health, Centers for Disease Control, Cal/OSHA, and USDA).

#### Laboratory Staff/Students

Laboratory staff and students are responsible for knowing the potential hazards of the biological material contained within their respective work areas, and the appropriate procedures and practices to be used in the laboratory. Laboratory employees must follow approved laboratory procedures and safety guidelines at all times.

Emergency Contact Information

Emergency Contact information should include the following information so that it is quickly and easily accessible:

1. Emergency Contact Information for:
	* Principal Investigator: Name and telephone number (24 hour/7 days per week)
	* Lab Supervisor(s): Name and telephone number (24 hour/7 days per week)
	* Biosafety Officer: (951) 827-4244 (during business hours)
	* Environmental Health & Safety (EH&S): (951) 827-5528 (during business hours)
	* Police: Emergencies - 911 (landlines) or 951-827-5222 (mobile phones)

 Non-emergencies – 951-827-5222

1. Locations of:
* Fire Alarms
* Fire extinguishers
* Eyewashes (Note: eyewashes should be flushed monthly)
* Emergency Showers (Note: showers should receive maintenance monthly)

Principles of Biosafety

According to the Center for Disease Control and Prevention publication, [*Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition*](http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf), a fundamental objective of biological safety program is the effective management of potentially harmful biological agents through the use of administrative and engineering controls such as containment. Administrative controls are management tools that provide staff with a set of guidelines describing how to safely operate with biological hazard(s) in an environment designed for containment of the hazard. The term "containment" is used in describing safe methods, facilities, and equipment for managing biohazardous materials in the laboratory environment where they are being handled or maintained. The purpose of containment is to reduce or eliminate exposure of laboratory staff, other individuals, and the outside environment to potentially hazardous agent(s). The risk assessment of the work to be done with a specific agent will determine the appropriate combination of these elements. For more information, refer to <http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf>.

Risk Assessment

Risk assessment is a process used to identify the hazardous characteristics of a known infectious or potentially infectious agent or material, the activities that can result in a person’s exposure to an agent, the likelihood that such exposure will cause a laboratory acquired infection, and the probable consequences of such an infection. The information identified by risk assessment will provide a guide for the selection of appropriate biological safety level(s) and microbiological practice(s), safety equipment, and facility protections that could prevent laboratory acquired infection or environmental escape. The risk assessment will determine the biological safety containment level (BSL) at which the work can be safely conducted.

A risk assessment should distinguish the following:

* Origin of material
* Pathogenicity of material: disease incidence and severity
* Route of transmission: airborne, ingestion, or parenteral,
* Concentration of working quantities and infectious organisms per ml of stock solution
* Infectious Dose
* Agent stability; how easily the material could be decontaminated
* Availability of prophylaxis (vaccination)
* Medical surveillance programs and exposure management (post-exposure prophylaxis)
* Staff knowledge and skill level including training

Additional risk assessment that may be needed include:

* Procedures being used that may produce an aerosol
* Procedures being used that may use needles or sharps
* If material has been concentrated or purified from cell cultures
* Use of larger volumes (>10Liters)
* If the research material has been altered, how does that affect the hazards associated with the material?
* Is the infectious material attenuated (to reduce the virulence/infectious nature of the material)?
* How could an exposure event occur?

Biological Safety Containment Levels

The following is a general understanding of the different biosafety levels and their relevant best practices is recommended.

#### Biosafety Level 1 (BSL-1)

BSL-1 is suitable for work involving well-characterized agents not known to consistently cause disease in immunosuppressed adult humans, and present minimal potential hazard to laboratory personnel and the environment. BSL-1 laboratories are not necessarily separated from the general traffic patterns in the building. Work is typically conducted on open bench tops using standard microbiological practices. Special containment equipment or facility design is not required, but may be used as determined by appropriate risk assessment. Laboratory personnel must have specific training in the procedures conducted in the laboratory and must be supervised by a scientist with training in microbiology or a related science.

#### Biosafety Level 2 (BSL-2)

BSL-2 builds upon BSL-1. BSL-2 is suitable for work involving agents that pose moderate hazards to personnel and the environment. It differs from BSL-1 in that 1) laboratory personnel have specific training in handling pathogenic agents and are supervised by scientists competent in handling infectious agents and associated procedures; 2) access to the laboratory is restricted when work is being conducted; and 3) all procedures in which hazardous aerosols or splashes may be created are conducted in biological safety cabinets (BSCs) or other physical containment equipment.

#### Biosafety Level 3 (BSL-3)

BSL-3 is applicable to facilities where work is performed with indigenous or exotic agents that may cause serious or potentially lethal disease through inhalation route exposure or serious damage to the environment if containment is breached. Laboratory personnel must receive specific training in handling pathogenic and potentially lethal agents, and must be supervised by scientists competent in handling the agents and associated procedures.

For more information, refer to Section IV of the [*Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition*](http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf)*.*

Spills in the laboratory

Each Principal Investigator/laboratory supervisor must develop specific spill cleanup methods tailored to the biological agent(s), quantities, and procedures being implemented in the lab, and ensure that the appropriate spill response material(s) is immediately accessible. The following recommended procedures may be utilized as a basis for cleaning spills of biological materials.

#### Minor (small) Biological Spill:

Steps to cleaning-up a biological spill:

1. Post the area where the spill occurred to avoid the potential for cross contamination and unnecessary exposure to others in or near the work area.
2. Since a spill has the potential to generate an aerosol, let the aerosol settle (minimum 30minutes)
3. Wear a laboratory coat and gloves and obtain or prepare fresh disinfectant solution for clean-up the spill (10 % bleach solution or EPA-Approved disinfectant).
4. Place paper towels or other absorbent material on top of the spill zone
5. Starting from the outermost edge of the spill and working in toward the center of the spill, pour disinfectant onto the absorbent material and allow sufficient contact time to destroy any biological contaminants. Contact time is range between 20 to 30 minutes refer to the instruction on the bottle of disinfectant.
6. Properly dispose of waste (including your gloves) in appropriate Biohazard waste containers lined with biohazard bag for final disposal.

#### Major Biological Spill:

Major Biological Spill is one that requires assistance of EH&S and/or external emergency personnel. Major Biological Spills involve releases of BSL2 or higher materials outside of a biological safety cabinet, or spills of such materials that involve excessive splashing or aerosol formation. Alert personnel in the laboratory of the spill, and prevent entrance of additional personnel by notification or posting of area. If any material has been splashed on you, if you have been exposed to the agent, or if any of your personal protective equipment has been breached, please follow the procedure outlined in the *Exposure Control Plan*:

1. Remove and disinfect any contaminated clothing.
2. Notify your supervisor and EH&S at 951-827-5528 of the incident.
3. If the situation involves an imminent life-threatening injury or a release outside the building; or has other catastrophic potential, call 911 to reach UCPD.
4. Have persons knowledgeable of incident and laboratory available to assist EH&S and/or emergency personnel.

Training

Laboratory staff should have both instructional and hands-on training for all biological hazards present in the laboratory and should demonstrate proficiency in techniques before being permitted to perform laboratory procedures independently.

#### General training

EH&S provides some online training courses, including the following:

* Bloodborne Pathogens (8 CCR 5193 / 29 CFR 1910.1030)
* Biosafety (introduction)
* Fire Extinguisher
* Hazardous Waste Management
* Laboratory Safety Orientation (Fundamentals) 2013
* Personal Protective Equipment (PPE): LHAT Safety Training

For more information, refer to <http://ehs.ucr.edu/training>.

#### Specific training

Laboratory-specific training should be provided by the PI, or senior scientist who has several years of experience working with the biological materials and can direct staff in safe handling of the materials to avoid any accidental exposures. All training sessions should be documented with the: training session topic(s), instructor, date, and attendees. Depending on the significance of the hazards involved, curriculum training and proficiency testing may be warranted.

Medical Surveillance

Depending on the biological materials manipulated in the laboratory, vaccinations and/or other medical surveillance programs may be warranted for employees. For more information on work-related injuries, you may review the “Injuries and Medical Treatment” flipchart located in each laboratory, which is also available online at <http://ehs.ucr.edu>.sonal Protective Equipment (PPE)

In addition to the required standard PPE in a BSL2 laboratory, other PPE may be required to safely manipulate the agent. In particular, you should consider additional PPE if you are manipulating animals and include this in your SOP.

The following is a list of common PPE found in the laboratory:

* Gloves
* Safety Glasses/Goggles
* Gowns/Aprons
* Laboratory Coat
* Respiratory protection (fit test and medical clearance required)
* Surgical Mask
* Shoe Covers
* Bonnets
* Face Shields

Warning Signs and Postings

Each laboratory must clearly display a sign that provides safety information to visitors and service personnel. For more information, contact the EH&S Biosafety Officer (951) 827-5528.

Biocontainment and Biological Safety Cabinets (BSCs)

The selection and use of BSCs are the primary means of containment developed for working safely with hazardous microorganisms. For more information, refer to Appendix A of the [*Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition*](http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf)*.*

Waste Disposal

Use this [guidance sheet](https://ehs.ucr.edu/waste/Biohaz%20Med%20Waste%20Disp%20Req_2016%200916.pdf%20) for appropriate disposal of biological materials, including medical waste and autoclave use. Additional information can be found online at <http://ehs.ucr.edu/waste>. All recombinant material is considered hazardous and must be disposed of as biological waste.

Housekeeping

Special practices include: decontaminating work surfaces after completing the work with the infectious materials, keeping non-research animals out of the laboratory, and reporting all spills and accidents.

Autoclaves

EH&S monitors autoclave effectiveness and performance on a recurring basis with *B.Stearothermophilus* indicators. To participate in the autoclave monitoring program, contact the EH&S Biosafety Officer (951) 827-4244. For more information about the effective use of autoclaves, refer to the Fast Facts available online at <http://ehs.ucr.edu> under “Resources” (Fast Facts for [*Effective Use of Autoclaves*](http://ehs.ucr.edu/resources/autoclaves.pdf)*).*

Needles and Sharps Precautions

* Substitute plastic ware, when possible
* DO NOT bend, shear, break, recap or remove needle from syringe
* Use sharps containers (don’t fill more than ¾ full), which must be located as close to work area as possible.
* Non-disposable sharps should be placed in a rigid container for transport to appropriate area for decontamination, such as by autoclaving
* Only needle-locking syringes or disposable syringe-needle units (needle is integral to the syringe) should be used
* Syringes that re-sheathe the needle, needleless systems, and other safety devices may also be used
* Do not handle broken glass directly by hand. Use a mechanical device such as forceps or protective gloves to pick up and dispose of glass in a glass box or sharps container

For more information, refer to <http://ehs.ucr.edu/biosafety>

Transportation of biological materials outside of the laboratory

Transportation of biological material(s) from one location to another (e.g. from one lab to another, between buildings, through common hallways) should be done in a primary container, with a secondary sealed and leak-proof container capable of containing the entire contents. Make sure to place a biohazard label on the primary container to identify the contents in the event the container is misplaced or dropped and spills.

Standard Operating Procedure

Instructions:

* Complete this template to develop a Standard Operating Procedure for your laboratory to address biological safety risks and place a hard-copy in the lab’s Biosafety Binder.
* All lab personnel must be trained on written Standard Operating Procedures (SOPs).
* Principal Investigators (PI) should use this template to specify laboratory specific procedures and document that personnel have been trained on those procedures.

|  |  |  |
| --- | --- | --- |
| Overview | Principle investigator (pi) name:  | Phone:  |
| Department | Office location: |
| laboratory location(s):*(Building, Room #), (Greenhouse #)* |
| Project title: | Bua #: |
| Sop revision date: |

responsibilities:

* Principal Investigator (PI): Ensure all procedures documented in this SOP are followed by all laboratory personnel.
* Laboratory Personnel: Follow all procedures as listed in this SOP.

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| biological agents and other infectious material | List all biological and infectious materials being used in this lab. *(i.e. human/non-human primate blood/cells/cell lines/ bacteria/ viruses, plant pathogens, etc.)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Agent*(E.coli bacteria)* | Risk Group*(1)* | Potential Hazards*(ingestion, mucous membrane exposure)* | Signs & Symptoms*(Diarrhea and stomach cramps; conjunctivitis)* | Required Immunization*(None)* |
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Resource to identify risk groups: <https://osp.od.nih.gov/wp-content/uploads/2013/06/nih_guidelines.pdf> |

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| Emergency response | Location of Nearest Emergency Equipment:

|  |  |
| --- | --- |
| Item: | Location |
| Eyewash / Safety Shower |  |
| First Aid Kit |  |
| Fire Alarm |  |
| Fire Extinguisher |  |
| Emergency Flip Chart |  |
| Available Telephone  |  |
| Fire Alarm Manual Pull Station |  |

 |
| Incident Response Procedures*Describe emergency procedure in the case of an accidental exposure. Procedures should include specific details for all possible route or exposures. (e.g. exposure via inhalation, via mucous membranes, via ingestion, etc.)* |
| **Emergency response** | Spill Response Procedures*Describe the procedures for the following spill types inside and outside containment (e.g biosafety cabinet, tissue culture hood, centrifuge, incubator, freezer, etc.) Specify the type of containment, include the disinfectant(s) and environmental and environmental decontamination procedures.*

|  |  |
| --- | --- |
| Spill Type | Spill Response Procedures |
| Minor spill inside BSC |  |
| Spill outside the BSC |  |
| Centrifuge |  |
|  |  |
|  |  |

 |
|  | Emergency Contacts (Phone numbers):

|  |  |
| --- | --- |
| Principal Investigator (PI): |  |
| Laboratory Supervisor: |  |
| Biosafety Officer: | (951) 827-4244 (during business hours) |
| EH&S: | (951) 827-5528 (during business hours) |
| **Police:** | **Emergencies** | **9-1-1** |
| **Non-emergencies** | **(951) 827-5222** |

Emergency contact |

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| training  | Training requirements are based on agents used:

|  |  |  |
| --- | --- | --- |
| Required EH&S Training | Is this applicable? | How Often? |
| Biosafety Training | YES |  |
| Bloodborne Pathogens Training |  | annual |
| Hazardous Waste Management | yes |  |
| Laboratory Safety Orientation (Fundamentals) 2013 | yes | every 3 years |
| Personal Protective Equipment (PPE): LHAT Safety Training | yes |  |
| Safety Orientation 2013 |  |  |

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| Additional Lab Specific Training |
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| --- | --- |
| Personal Protective Equipment (PPE) | list all Personal Protective Equipment (PPE) required to work in this lab. *(e.g. Entry and exit procedures, use PPE during work, removal and proper disposal)*  |

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| --- | --- |
| General Laboratory Work Practices and Procedures | general Laboratory Work Practices & Proceduresonmental decontamination procedures.rcinogens).*Describe general laboratory work practices including proper storage and handling of biological agents, proper use of equipment, etc. Specify locations where procedures and handling of biological agents will take place.*  |

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| Engineering Controls | Engineering Controls*Describe the applicable engineering controls that will be used to minimize the risk of exposure to biohazardous materials.*

|  |
| --- |
| **Biological Safety Cabinet(BSC)** |
| Building  | Room Number | Make | Model | Serial Number | Date Last Certified |
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| --- | --- | --- | --- |
| Building  | Room Number | Make | Model |
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| --- |
| **Other:**  |
| Building  | Room Number | Make | Model | Serial Number | Date Last Certified |
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| Decontamination Procedures | Decontamination Procedures*List all disinfectants and decontamination procedures that will be used in the lab.* |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Waste | biological waste and Disposal Methods onmental decontamination procedures.rcinogens).*Describe how each of the following biological wastes will be disposed of in the lab, as applicable.*

|  |  |
| --- | --- |
| Waste Type | Disposal Procedures |
| Solid Waste |  |
| Sharps Waste |  |
| Liquid Waste |  |

 |

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| --- | --- |
| Transportation | Specimen transport and removal of material(s) from the laboratoryonmental decontamination procedures.rcinogens).*(Describe the procedures for transportation of biological samples within campus and/or off-campus.)*  |

**HEPATITIS B VACCINATION (HBV)**

In compliance with the California Occupational Safety and Health Administration (Cal/OSHA) Bloodborne Pathogens (BBP) Standard ([8CCR§5193](https://www.dir.ca.gov/title8/5193.html)), the University of California, Riverside encourages employees who may be potentially exposed to bloodborne pathogens to be vaccinated. The Hepatitis B vaccination (HBV) shall be made available at no cost to the employee, after the employee has received the required training and ***within ten (10) working days*** of their initial assignment. The immunization is made available to all employees who may have occupational exposure unless the employee has previously received the complete Hepatitis B vaccination series, antibody testing has indicated that the employee is immune, the vaccine is contraindicated for medical reasons, or the employee signs the HBV declination form. The Hepatitis B Vaccination Request/Declination Form (available on the EH&S website: [ehs.ucr.edu](file:///%5C%5CFBOAD%5CDepartments%5CEHS%5CBiosafety%20Program%5CSOPs%5Cehs.ucr.edu)) should be completed and signed by both the employee and supervisor.

If the employee initially declines the Hepatitis B vaccination but at a later date, while still covered under the Cal/OSHA Bloodborne Pathogens Standard, decides to accept the vaccination, the Hepatitis B vaccination shall be made available at that time. Hepatitis B vaccination declination should be kept in secure storage with the Principle Investigator.

If a routine booster dose(s) of Hepatitis B vaccine is recommended by the U.S. Public Health Service at a future date, such booster dose(s) shall be made available.

**SIGN OFF DOCUMENTATION**

**Principal Investigator Certification:**

I hereby certify that I have reviewed these practices and procedures and they represent the current operating practices in my laboratory.

|  |  |  |
| --- | --- | --- |
| Print name: | Signature: | Date:  |

**Personnel Certification:**

We, the undersigned, have reviewed these practices and procedures, have been trained in the appropriate methods and practices for handling potentially infectious material and agree to follow the state practices and procedures. We understand that we must review and document compliance with these practices and procedures on an annual basis.

|  |  |  |
| --- | --- | --- |
| **Personnel Name** | **Personnel Signature** | **Date** |
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Additional Resources for Information

Resources for information, consultation, and advice on biohazard control, decontamination procedures, and other aspects of laboratory and animal safety management include:

*Centers for Disease Control (CDC)*

*Biosafety in Microbiological and Biomedical Laboratories (BMBL)*

Office of Health and Safety (Mailstop: F-05)

1600 Clifton Road

Atlanta, Georgia 30333

Telephone: (404) 639-7233

Fax: (404) 639-2294

Website: <http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf>

*AAALAC International*

Association for Assessment and Accreditation of Laboratory Animal Care International

5283 Corporate Drive, Suite 203

Fredrick, MD 21703-2879

Telephone: (301) 696-9626

Fax: (301) 696-9627

Website: <http://www.aaalac.org>

*American Biological Safety Association*

1200 Allanson Road

Mundelein, IL 60060-3808

Telephone: (847) 949-1517

Fax: (847) 566-4580

Website: <http://www.absa.org/>

*CDC Etiologic Agent Import Permit Program*

Centers for Disease Control and Prevention

Etiologic Agent Import Permit Program (Mailstop: F-46)

Atlanta, Georgia 30333

Telephone: (404) 718-2077

Fax: (404) 718-2093

Website: <http://www.cdc.gov/od/eaipp/>

*Select Agents General Information*

Website: <http://www.selectagents.gov>