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**Standard Operating Procedure Requirements for**

**BSL2 and/or ABSL2 Containment**

***The Principal Investigator (PI) has the responsibility to inform the laboratory personnel of the appropriate research procedures. When using hazardous or regulated biological agents the PI must prepare a written Standard Operating Procedure (SOP) outlining the necessary precautions to safely conduct research. An SOP is a set of specific guidelines designed to address the methods that will be used and the safe handling of biological agents. The SOP must be available in the laboratory and in the approved Animal Component of Research Protocol (ACORP).***

***The SOP is a valuable tool and worth the preparation time. A well-written SOP can be used to satisfy several compliance requirements. SOP should be written for all procedures that pose an identified potential risk to the health and safety of the laboratory personnel, although a separate SOP does not need to be written for each individual experiment, procedures with the same hazards can be combined into one SOP.***

***The process of writing SOPs requires an individual to think through all steps of a procedure and perform a risk assessment before work has begun. The best approach to writing an SOP is to do it, write it and test it. Be brief and succinct; the shorter the better. An SOP template is provided below.***

***ABSL2 and BSL2 requirements also include appropriate biohazard labeling. An example of appropriate signage for a door is attached at the end of the template for your use. Remember, other signs may also be appropriate, as long as they include the necessary information (Biohazard Symbol, Biocontainment Level, name of agent and any necessary requirements to take prior to entering or exiting the lab, and PI and lab contact information).***

***Approval or exemption from IACUC Hazardous Agents Subcommittee is required for ABSL-2, BSL-2, and/or Chemical Agents. Please consult with subcommittee via email to*** *hazardousagents@luc.edu****.***

**Sample Standard Operating Procedure Template for Safe Handling of**

**(*List organisms and/or animals)* at BSL2/ABSL2 [*select appropriate* *environment(s)]* Containment**

*Please edit and complete as necessary to address Biosafety Risks within your laboratory and/or animal housing area.*

**Title of Procedure**: *One safety SOP can be used for more than one experimental protocol if the material, equipment being used and potential hazards are the same.*

**Introduction and Purpose of Work:** *Provide a brief description of work.*

***If you are working with viral vectors and claiming replication deficiency, please provide details describing confirmation of competency testing. Otherwise, the same biosafety precautions and animal housing requirements must be followed as used for the wild type virus.***

|  |  |
| --- | --- |
| PI: | Lab Location: *(Building and room number)* |
| Work Phone: | Animal Housing Location: *(Building and room number)* |
| IACUC#: | Species: |
| Issue Date: | Revision Date: |
| Prepared by: | IBC Approval (if applicable):  |

**Applicable Regulatory Statutes / Guidelines:** *List only the appropriate.*

[***Examples:*** Export Control (<http://www.bis.doc.gov/licensing/exportingbasics.htm>), Select Agent Rules (<http://www.cdc.gov/od/sap/>), OSHA Bloodborne Pathogens Standard (<http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051>) , CDC/NIH’s Biosafety in the Microbiological and Biomedical Laboratories (<http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm>)

NIH rDNA Guidelines:<http://oba.od.nih.gov/rdna/nih_guidelines_oba.html>]

**RISK ASSESSMENT:**

**Hazard Identification and Risk of Exposure to the Hazards:** *Describe the risk of the agents being handled in the laboratory. If applicable, describe the signs and symptoms of illness and/or disease. Determine if immunization is needed.*

**Routes of Transmission:** *Prior to assigning containment requirements, it is imperative to understand the routes of transmission.*

 **Some issues to address:**

*1. What are the exposure routes/risks of most concern?* (**Examples:** Sharps exposures, Splash exposures, Non-intact skin exposures, other exposures such as food, drink, inanimate objects).Describe the sharps and fragile glass items that will be used (i.e. capillary tubes, needles, glass pipettes, Pasteur pipettes).

*2. If applicable, are there any off target effects (insertional mutagenesis, etc.) from exposure to the biohazardous and/or recombinant material??*

*3. What are the consequences of exposure to the biohazardous and/or recombinant material?*

**MEDICAL CONSIDERATIONS:**

**Medical Screening and Surveillance** *(if necessary):*

*Personnel may also be offered vaccines or special counseling depending on the organism(s) handled in the lab and availability of vaccines or prophylaxis.*

Accidental exposures, such as splash to the face or a sharps injury shall be reported immediately to Employee and Student Health by dialing **1-888-LUHS-888 (1-888-584-7888)**. The representative will help categorize the risk of developing occupationally-acquired infection and provide advice on an appropriate post-exposure treatment.

**PRECAUTIONS:**

***All laboratory work shall fully comply with biosafety level 2 (BSL2) containment as described in the current edition of the CDC/NIH’s Biosafety in the Microbiological and Biomedical Laboratories:*** [*http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm*](http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm)

**Procedural Methods and Materials**: *Incorporate each category as it pertains to your work:*

**Door Signage & Equipment Labeling:** (*ex., doorway, refrigerators, incubators, cage signs*)

* 1. Posting of signs is research staff’s responsibility!
	2. Signs will be posted at all times when hazardous material is present.
	3. Signs will be removed by research staff when hazardous material is no longer present.

**Access to laboratory**: (*ex., describe restrictions, locks*.)

**Personal Protective Equipment (PPE)**: (*describe entry and exit procedures to include donning and doffing (removing) PPE before leaving the work area; list/describe the PPE worn*)

**Methods to minimize personal exposure:** (work practices: *Describe alternatives to sharps/safer devices that will be used, explain the use of conveniently located sharps waste containers and absorbent material on countertops to contain spills, leaks*)

**Methods to prevent the release of infectious agents/protect workers from aerosols, splashes, splatters**: (describe equipment/engineering controls: *ex., Class II Biological Safety Cabinets (BSC), covered centrifuge cups*)

**Specimen transport and removal of material(s) from the laboratory:** (*ex., leak proof transport containers*)

**Standard microbiological methods:** (*ex., handwashing after removal of gloves and before leaving the work area, no mouth pipetting, no food or drink in refrigerators where material is stored, no eating in work area*)

**Cleaning & Disinfection:** *Describe surface decontamination, cleaning procedures and type of disinfectant(s) used (i.e. 1:10 household bleach).*

**Waste Generation and Disposal Methods:** *Identify the types of waste generated (liquid waste, dry waste, sharps waste, animal carcasses) and procedures for handling/disposing of biological waste including contaminated, non-contaminated waste and use of sharps containers.*

**Spill and Accident Response Procedure:** *Describe all emergency procedures including spill clean-up. Describe**disinfectant (dilutions/contact times) and environmental decontamination procedures.*

For Example, Outside of a BSC*:*

*If spill is a respiratory hazard, (this risk should be described under RISK ASSESSMENT*) mark the area as SPILL, DO NOT ENTER and evacuate 30 minutes to allow aerosols to settle. After 30 minutes, proceed with the following.

Place absorbent towels over the spill, apply freshly prepared 1:10 bleach*\** solution to entire area of spill starting on the outer edges and working inward, contact time: 10 minutes, pick up sharp items with mechanical device (not hands), place disposable sharp items in sharps waste container and non-sharps clean-up materials in a leak-resistant disposable bag. Repeat the process to ensure complete decontamination of organic material. *\*Large amounts of household bleach should not be autoclaved.*

 **Personnel Exposure to Biohazards**

1. Report exposure by calling the **1-888-LUHS-888 (1-888-584-7888), Employee and Student Health**
2. Complete the Report of Occupational Injury found at <http://www.luc.edu/hr/online_forms.shtml>

**TRAINING:**

**Training Requirements**: *Workers conducting research under this procedure must comply with the following training requirements:*

* Complete online Laboratory Safety-General training provided by Office of Research Services (ORS) at medtraining.org. This training is required annually and is documented by ORS.
* Complete the online Biosafety Training for Lab Workers.
* All personnel shall read and fully adhere to this SOP.
* ***P.I. will keep documentation of personnel reading and understanding this lab-specific SOP using a signature page (example attached).***

**For animal use only**

**PRECAUTIONS:**

***All animal work shall fully comply with animal biosafety level 2 (ABSL2) containment as described in the current edition of the CDC/NIH’s Biosafety in the Microbiological and Biomedical Laboratories:*** [*http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm*](http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm)

**Required Procedures for Work in ABSL2 Animal Facilities:**

The researcher is responsible for:

1. Communicating the start date of the study and conveying the **approved** **SOP** for the animal work to the *Assistant Director,* *CMF*

**This communication must occur at least two (2) business days prior to initiation of the work**.

1. Initiating the work only after obtaining confirmation that your notification has been received.
2. **Placing the proper signs** on the animal room door and cages prior to the initiation of the study.
3. Removing the signs when the study is complete.
* **Cage Cards and Door Signs:** As soon as the animals have been dosed with the biohazardous agent, cages must be marked with the biohazard cards **and** the attached sign must be posted on the outside of the animal room door by research staff. This sign will be removed by research staff once the infected animals and biohazardous agents are no longer in the animal room.

**Researcher’s Procedures in the ABSL2 Animal Facility:** *Describe procedures done within the animal facility and engineering controls used such as a biological safety cabinet.*

* *EXAMPLE*: Animals will be dosed intranasally with the biohazardous agent. All work with the biohazardous agent will be done within a Class II biological safety cabinet.

**Animal Cage-Change Procedures:**

**NOTE:** **at ABSL2**, c**age changes will be confined to a ventilated cage changing station or biological safety cabinet and unless otherwise instructed by the IACUC, research staff will change cages.**

**Standard ABLS2 cage change procedures:**

1. Cages will be changed by research staff no sooner than 72 hours after the animals are exposed to the biohazardous agent.

b. Cages (with bedding) will be bagged in red biohazard bags and taped shut.

1. CMF staff will transport bagged cages to autoclave.
2. Only after cages have been autoclaved will they be dumped as normal waste.

**Exceptions to Standard CMF ABLS2 cage change procedures:**

*Describe necessary changes to the standard CMF ABSL2 cage changing procedures*

* + *EXAMPLE:* CMF Staff may change cages 72 hours after administration of this agent.
	+ *EXAMPLE:* Bleach is the only disinfectant recommended when working with this agent.

**For Lab use**

*Example of appropriate signage for BSL2 laboratory doorway:* ***PLEASE COMPLETE***

**AUTHORIZED PERSONNEL ONLY!**



BIOHAZARD

**2**

BIOSAFETY LEVEL

Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Agent (s): \_\_\_*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Bldg: \_\_\_\_\_\_\_\_\_\_\_ Room: \_\_\_\_\_\_\_\_\_\_\_\_\_ (space must be approved by CMF)

|  |
| --- |
| Special Instructions/ Requirements Prior to Entry or Exit (*i.e. personal protective equipment, vaccination*): |

|  |  |  |  |
| --- | --- | --- | --- |
| **EMERGENCY CONTACT/ ADVICE** | **CONTACT** | **WORK PHONE** | **HOME PHONE****or PAGER** |
| Primary |  |  |  |
| Secondary |  |  |  |
| Bio-safety Officer | Matthew Hejna | 66738 | 11411 |

**For animal use**

*Example of appropriate signage for ABSL2 laboratory doorway:* ***PLEASE COMPLETE***

**AUTHORIZED PERSONNEL ONLY!**



BIOHAZARD

**2**

ANIMAL BIOSAFETY LEVEL

Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Agent (s): \_\_\_*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Bldg: \_\_\_\_\_\_\_\_\_\_\_ Room: \_\_\_\_\_\_\_\_\_\_\_\_\_ (space must be approved by CMF)

|  |
| --- |
| Special Instructions/ Requirements Prior to Entry or Exit (*i.e. personal protective equipment, vaccination*): |

|  |  |  |  |
| --- | --- | --- | --- |
| **EMERGENCY CONTACT/ ADVICE** | **CONTACT** | **WORK PHONE** | **HOME PHONE****or PAGER** |
| Primary |  |  |  |
| Secondary |  |  |  |
| Bio-safety Officer | Matthew Hejna | 66738 | 11411 |

*Example of Signature Page:*

**Standard Operating Procedure for Handling**

**[*List organism(s)*] at BSL2/ABSL2 [*circle appropriate environment(s)*] Containment**

**“I have read and understand this SOP. I agree to fully adhere to its requirements.”**

