**Standard Operating Procedure Requirements for**

**BSL-2 work at the**

**University of Montana**

**Justification**

Template revised 20240626

***NOTICE:***

***This is a blank SOP TEMPLATE. It has not been completed for you. You must complete the sections of this template with your text and submit the draft for review by the BSO – Biosafety Officer (***[***IBC@mso.umt.edu***](mailto:IBC@mso.umt.edu)***). Notes in the margin provide help for completing the SOP and some are in red text for emphasis.***

***The Principal Investigator (PI) has the responsibility to inform the laboratory and other research 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 readily available where the work is conducted.***

***The SOP is a valuable tool and worth the preparation time. A well-written SOP can be used to satisfy several compliance requirements. An 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 SOP(s) 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. Please use the prompts and notes in the comments in the right margin for guidance and then DELETE the comments once you have completed the DRAFT SOP prior to sending to the BSO – Biosafety Office (***[***IBC@mso.umt.edu***](mailto:IBC@mso.umt.edu)***).***

***BSL-2 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.***

**An acknowledgment signature page is included. Do not sign until the BSO or IBC has approved the SOP. Once the SOP is finalized as a pdf by the BSO and sent back to you, review the SOP with staff and have each person sign the page.**

**The preparer may delete this justification after reading it and upon completion of the SOP.**

**Standard Operating Procedure for Safe Handling of**

**( ) at BSL-2 Containment**

**Title of Procedure**:

**Introduction and Purpose of Work:**

|  |  |
| --- | --- |
| PI: | Lab Location(s): |
| Issue Date: | Revision Date (within 3 years): |
| Prepared by: | BSO (Biosafety Officer) Approval Signature: |

**Applicable Regulatory Statutes / Guidelines:**

**RISK ASSESSMENT:**

**Hazard Identification:**

**Risk/Routes of Exposure and Consequences of Exposure**

**MEDICAL CONSIDERATIONS:**

**Medical Screening and Surveillance***:*

Accidental exposuressuch as splash to the face, sharps injury and/or exposure to an infectious agents shall be reported immediately to PI or supervisor and a “First Report of Injury” filed with MUS Workers Compensation Program 406-243-2842, within 24 hours. Medical care and assistance can be obtained at Curry Health Center (9am-4pm weekdays) or other emergency facilities, if necessary.

Workers with concerns or questions about their individual risk factors related to this work with the biological materials are encouraged to consult with Environmental Health and Risk Management or Curry Health Center.

**PRECAUTIONS:**

***READ: All laboratory work shall fully comply with biosafety level 2 (BSL2) containment as described in the current edition of the guideline: CDC/NIH’s Biosafety in the Microbiological and Biomedical Laboratories:*** [***https://www.cdc.gov/labs/BMBL.html***](https://www.cdc.gov/labs/BMBL.html)

**PROCEDURAL METHODS and MATERIALS**:

**Door Signage & Equipment Labeling:**

* 1. Posting of signs is the research staff’s responsibility!
  2. Signs will be posted at all times on equipment and at room entry when hazardous material is present.
  3. **Signs will be removed by research staff when hazards are no longer present**.

**Access to laboratory and equipment**:

**Personal Protective Equipment (PPE)**:

**Methods to minimize personal exposure:**

Do not use personal electronic devices (non-medical) while working with biological materials to reduce risk of contamination and exposure.

**Methods to prevent the release of infectious agents/protect workers from aerosols, splashes, splatters**:

**Specimen transport and removal of material(s) from the laboratory:**

**Standard microbiological methods required:**

Vacuum lines equipped with an in-line HEPA filter or equivalent as well as a primary and secondary collection flasks will contain a 10% (final concentration of at least 0.5% sodium hypochlorite when mixed with cell culture media waste) bleach solution.

**Cleaning & Disinfection**:

**Waste Treatment and Disposal Methods:**

*Liquid (e.g., culture and media, etc.) waste is treated with 1:10 germicidal bleach for 30 minutes before being carefully poured down the drain (while wearing full face protection), followed by a copious amount of water to prevent corrosion.*

*Solid disposal items are placed in an autoclavable bag that is loosely closed to allow for steam penetration. The bag is then placed in a secondary autoclavable tray/open bin (to prevent or contain leaks) and* ***autoclaved for 90 minutes at 121oC, 15 p.s.i.*** *After autoclaving, the biohazard symbol on the bag is defaced and placed in a black trash bag before disposal in the trash or building dumpster.*

*Sharps (e.g., needle with syringe, blades, and Pasteur pipettes) are placed into a conveniently located puncture-resistant, autoclavable (vented) biohazard sharps container, closed when < 2/3 filled, and autoclaved for 90 minutes at 121oC, 15 p.s.i. before contacting* Environmental Health at **406-243-4503***for pickup and disposal.*

**Spill, Accident Response and Sharps Injury Procedure:**

**Personnel Exposure to Biohazards**

1. Mucous membrane (eyes, nose, or mouth): Rinse at the nearest emergency eyewash station for 15 min.
2. Skin: Wash with soap and water for 15 min.
3. If warranted, seek medical attention at Curry Health Center or other urgent care facility.
4. Report exposure by filing ‘First Report of Injury’ with Worker’s Compensation (**406-243-2842**) within 24 hours. <https://www.umt.edu/human-resources/employee-resources/workerscomp/workers-comp-procedures.php>
5. In the event of a laboratory-acquired infection, appropriate treatment will be determined by treating healthcare professionals.

**TRAINING:**

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

* 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).***

|  |  |  |  |
| --- | --- | --- | --- |
| Type of work | Requirements | Course(s) | Who |
| **All Laboratory Work** | All lab personnel | 1. [UM’s Lab Safety Training and Quiz](https://www.umt.edu/environmental-health/labsafety/) (taken one time at the initiation of lab work.) 2. CITI-laboratory chemical safety 3. CITI- Initial Biosafety (one time) 4. CITI-Biosafety retraining (annually) 5. UM Chemical Hygiene Plan review | All faculty, staff, students, or other individuals working with any biohazardous materials and/or working in a laboratory. |
| **Work with Animals** | Required in addition to animal training if working with hazardous/infectious materials | CITI-animal biosafety  *\*plus additional animal training requirements (see IACUC)* | All faculty, staff, students, or other individuals working with animals and hazardous/infectious agents |
| **Field Work with Animals** | Required if working with potentially infectious samples | 1. CITI- Initial Biosafety (one time)  2. CITI-biosafety retraining (annually)  *\*plus additional animal training requirements (see IACUC)* | All faculty, staff, students, or other individuals working with any potentially infectious samples in the field |
| **Work with recombinant or synthetic DNA** | Required if working with  s/rNA | CITI- NIH Recombinant DNA (rDNA) Guidelines | All faculty, staff, students, or other individuals working r/sNA molecules |
| **Work with blood/fluid/cells** | Required if working with blood/fluid/cells from human or non-human primates | CITI- OSHA Bloodborne Pathogens (annually) | All faculty, staff, students, or other individuals working with occupational exposure to human blood or other potentially infectious materials |

**For Lab use**

**AUTHORIZED PERSONNEL ONLY!**

**2**

A black and orange sign with black text

Description automatically generated

**BIOSAFETY LEVEL**

Principal Investigator:

Biological Material(s):

Bldg:       Room:

|  |  |  |  |
| --- | --- | --- | --- |
| Special Instructions/ Requirements Prior to Entry, Working, or Exit (*i.e. personal protective equipment, vaccination*):  PPE worn prior to entry:  During work with or near biological material:  REMOVE PPE AND WASH HANDS BEFORE LEAVING THE WORK AREA. | | | |
| EMERGENCY CONTACT/ADVICE | CONTACT | WORK PHONE | After hours PHONE |
| PRIMARY |  |  |  |
| SECONDARY |  |  |  |
| Departmental Contact  (if necessary) |  |  |  |

***Signature Page:***

**Standard Operating Procedure for Safe Handling of**

**( ) at BSL-2/Containment**

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Last Name** | **First Name** | **790-#** | **Signature** |
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