

BSL2 Laboratory Protocol-Specific Operations Manual (POM)

Supplement to the Biosafety Guide for BSL2 Laboratories

Protocol ID#:

This form details project-specific materials, processes and hazards associated with the indicated biosafety protocol conducted in the BSL-2 laboratory. It expands the general directions found in the Biosafety Guide for BSL-2 Laboratories (aka the "Guide") and must be present in the associated BSL2 laboratory space(s) as a hard copy or in electronic form on a laboratory computer.

PRINCIPAL INVESTIGATOR, LABORATORY DIRECTOR or INSTRUCTOR

Name:

Phone:

PROJECT TITLE:

1. Laboratory points of contact

Laboratory Supervisor Name:

Phone:

2. Materials in Use

- a. Recombinant or synthetic DNA or other nucleic acid molecules

No

Yes

If *Yes*, insert the Materials table(s) prepared for Protocol Form A, *Use of Recombinant or Synthetic Nucleic Acid Molecules in Research* for each material intended for use under this protocol.

- b. Infectious Agents

No

Yes

If *Yes*, insert the Agent table(s) for each infectious agent intended for use under this protocol or enter the materials previously listed on Form B, *Use of Infectious Agents, Toxins and Select Agents in Research*.

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c. Biological Toxins

No Yes

If *Yes*, insert the Toxins table(s) for each infectious agent intended for use under this protocol or enter the materials previously listed on Form B, *Use of Infectious Agents, Toxins and Select Agents in Research* for each biological toxin intended for use under this protocol.

d. Select Agents

No Yes

If *Yes*, insert the select agent table(s) for each infectious agent intended for use under this protocol or enter the materials previously listed on Form B, *Use of Infectious Agents, Toxins and Select Agents in Research* for each select agent intended for use under this protocol.

e. Materials derived from Humans or Non-human Primates (NHP)

No Yes

If *Yes*, insert the Materials section from Form C, *Human and Non-Human Primate Blood, Cell Lines, or Other Potentially Infectious Materials (OPIM)* for each material intended for use under this protocol.

3. Training Requirements

Will personnel be working with, or exposed to, *any* of the potentially infectious or hazardous materials listed above?

No Yes

Individuals working with blood, blood components or other bodily fluids derived from humans or non-human primates (NHP), or any human or NHP cells or cell lines known or suspected to be infected with agents that cause disease in humans, must:

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- complete CITI Bloodborne Pathogen training on an annual basis. *Documentation of training completion must be maintained with this manual.* The PI or Lab Supervisor must provide copies to the IBC or EH&S upon request.
- be provided information about the Hepatitis B vaccine to include: efficacy of the vaccine, its safety, method of administration, benefit of administration, benefits associated with vaccination. Also, personnel will be encouraged to obtain the vaccine from their personal physician.
- familiarize themselves with the following exposure incident information:
 - i. An exposure incident is defined as a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that resulted from the performance of an employee's duties.
 - ii. If exposed to blood or other potentially infectious materials, first determine if it meets the definition of an exposure incident. Blood or fluids splashed onto intact skin are not exposure incidents, but require skin to be washed immediately.
 - iii. Exposure to saliva that is not visibly contaminated with blood does not constitute an exposure incident. If it is determined that an exposure incident has occurred, the exposed employee will immediately report the incident to his/her supervisor or the PI.
 - iv. Laboratory workers must report any exposure incident as soon as is reasonably possible to the project's Principal Investigator (or the PI's designated Laboratory Supervisor) who is then responsible for informing the ISU Biosafety Officer or EH&S. The worker will report to their personal physician or an emergency department for post exposure evaluation and follow-up.

4. Procedures for BSL2 Laboratories

A. Access to this Laboratory

- a. Access to this BSL-2 laboratory is restricted to those persons approved by the Principal Investigator when work with BSL-2 agents or materials is in progress.
- b. Does entry into this laboratory require participation in a medical surveillance plan?

Yes

No

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If Yes, describe the Medical Surveillance Plan below:

c. Does entry into this laboratory require vaccination against one or more infectious agents?

Yes No

If Yes, list the agents in box below:

B. Handling of Sharps

1. Will **Non-disposable** sharps be used in this lab? Yes No

a. If *Yes*, list the types of non-disposable sharps used:

b. Describe how **non-disposable sharps** that become contaminated with infectious material will be transported to a decontamination area and the methods used for decontamination. If not applicable, insert NA.

C. Decontamination and Disposal of Hazardous Waste

a. Decontamination of Work Surfaces and Equipment: *Work surfaces and equipment that come into contact with biohazardous material must be decontaminated immediately after use and before repair, maintenance, or removal from the laboratory.*

Describe the method(s) to be used for decontamination of work surfaces and equipment:

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b. Liquid Waste

Describe the method(s) to be used for decontamination and disposal of **liquid** biohazardous waste:

NA

c. Solid Waste

Describe the method(s) to be used for decontamination and disposal of **solid** biohazardous waste:

NA

d. If an autoclave will be used to decontaminate solid or liquid waste, complete the table below, otherwise check NA:

Model or ISU equipment ID	Location (Bldg & Room #)	Person responsible for quality assurance testing & maintenance

D. Transport and Shipping of BSL-2 Agents

a. If potentially hazardous or infectious materials will be transported or shipped between locations (e.g., rooms, laboratories, campuses, etc), complete the information below (add rows as needed), otherwise skip to item 5.

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Material(s)	Quantity / Volume	Location (From)	Destination (To)	Method of Transport

- b. Describe the primary and secondary containment measures for transporting/shipping of these materials/agents.

- c. Identify the person(s) responsible for transport or shipping and provide date of CITI training for Hazardous Materials Shipping.

5. Containment Procedures

Will procedures or equipment be used that increase the risk of generating aerosols of biohazardous materials? Yes No

Examples include, but are not limited to, centrifugation, sonication, shakers, use of positive pressure devices to disrupt, dissociate or filter hazardous materials, etc.

- a. If *yes*, describe the procedures or equipment to be used and the methods of containment:

- b. Will a biological safety cabinet be utilized? Yes No

- I. If *yes*, complete the table and other information below.

BSC Model or ISU Equipment ID	Location	Certification Date

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II. If applicable, describe the use of UV light in the BSC.

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III. If applicable, describe the use of vacuum traps in the BSC.

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6. Procedures for Visitors and Volunteers

Volunteers at ISU must comply with the requirements of **ISUPP 3020, University Volunteer Policy**, or the current equivalent. PIs and/or their designated Laboratory Supervisors are responsible for knowing and implementing the current policy for all volunteers, and have a signed Volunteer waiver and agreement in place, before the volunteer begins work in the laboratory.

Copies of the Volunteer waivers and agreements should be added to this Operations form when submitted for IBC review.

Visitors fall under the requirements of **ISU 7110 ISU Laboratory Safety policy**. It defines a Visitor – A person, including school-aged children (i.e. school tours), present in a laboratory under escort, to observe, but not to use or work in the facility. These persons are in a laboratory on a short-term basis, do not require releases or agreements to be present, only if the PI or laboratory supervisor has approved their visit in advance and has arranged for their escort while in the laboratory. If not directly affiliated with the research work in a specific laboratory, an ISU employee is considered a visitor and shall be the responsibility of the inviting PI.

7. Safe Use and Maintenance of Laboratory Equipment

There are many different types of basic and advanced laboratory equipment used on the ISU campuses. It is the responsibility of the Principal Investigator and/or his/her

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designated Laboratory Supervisor to ensure that all authorized users are properly trained on the use and maintenance of said equipment, especially when during and after processing of biohazardous materials.

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Principal Investigator Certification

The Principal Investigator on this protocol certifies the following:

I understand my duties and responsibilities relating to this protocol and as described above.

The information provided in this document is a complete listing of the specific materials and requirements for the protocol indicated.

A copy of this POM, plus a copy of the Guide, shall be maintained in the laboratory during the ongoing work described in this approved protocol.

PI Signature: _____

Laboratory Worker Certification

Each laboratory worker assigned to this protocol certifies the following:

We, the undersigned, have reviewed the Biosafety Guide for BSL-2 Laboratories (the "Guide") and this Protocol-specific Operations Manual (POM).

We have been trained in the appropriate methods and practices for handling those potentially infectious or other biohazardous materials in use in this laboratory and are aware of the risks of this work.

We agree to follow the stated approved practices and procedures in both the Guide and this POM.

We further agree to review these documents and the laboratory's practices and procedures **on an annual basis**.

Name: Lab Personnel Name. Signature and Date: _____

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