# Standard Operating Procedure

# Biosafety Level 2

**This is an SOP template and is not complete until: 1) lab specific information is entered into the box below 2) lab specific protocol/procedure is added to the protocol/procedure section and
3) SOP has been signed and dated by the PI and relevant lab personnel.**

Print a copy and insert into your *Lab-Specific Biosafety Plan*.

## Section 1 – Lab-Specific Information

| **Department:** | Click here to enter text. |
| --- | --- |
| **Date SOP was written:** | Click here to enter a date. |
| **Date SOP was approved by PI/lab supervisor:** | Click here to enter a date. |
| **Principal Investigator:** | Click here to enter text. |
| **Internal Lab Safety Coordinator/Lab Manager:** | Click here to enter text. |
| **Lab Phone:**  | Click here to enter text. |
| **Office Phone:** | Click here to enter text. |
| **Emergency Contact:** | Click here to enter text. |
| *(Name and Phone Number)* |
| **Location(s) covered by this SOP:****Biohazardous Agents covered by this SOP*:*** | Click here to enter text. |
| *(Building/Room Number)**Click here to enter text.* |

## Section 2 – Type of SOP:

[ ]  Process [x] Biosafety Procedure [ ]  Hazardous Class

## Section 3 – Biosafety Level 2 Requirements

* Laboratory personnel have specific training in handling pathogenic agents and are supervised by scientists competent in handling infectious agents and associated procedures; access to the laboratory is restricted when work is being conducted; and all procedures in which infectious aerosols or splashes may be created are conducted in a biosafety cabinet (IIA2 or IIB2) or other physical containment equipment.
* The laboratory supervisor must enforce the institutional procedures that control access to the laboratory.
* Lab staff must wash their hands after working with potentially hazardous materials and before leaving the laboratory.
* Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption is not be permitted in laboratory areas. Food must be stored outside the laboratory area in cabinets or refrigerators designated and used for this purpose.
* Mouth pipetting is prohibited; mechanical pipetting devices must be used.
* Perform all procedures to minimize the creation of splashes and/or aerosols.
* Plastic ware should be substituted for glassware whenever possible.
* An effective integrated pest management program is required.
* Animal and plants not associated with the work being performed must not be permitted in the laboratory.
* An eyewash station must be readily available.

**Section 4 – Agent Awareness**

Review the REM supplied agent risk assessment with all staff that will be exposed either through direct handling or proximity. Signs and symptoms, transmission routes, personal protective equipment, decontamination, and accident/exposure information will be covered.

All laboratory personnel and particularly women of childbearing age should be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify to the institution’s healthcare provider for appropriate counseling and guidance.

The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties and demonstrate proficiency in standard and special microbiological practices before working with BSL2 agents.

Personnel must receive annual updates or additional training new biohazards are added or other lab changes occur.

All persons entering the laboratory must be advised of the potential hazards and meet specific personal protection requirements.

## Section 5 – Personal Protective Equipment (PPE)

At a minimum, gloves, outerwear (single use when directly handling high hazards), eye protection, and if necessary respiratory protection (a fit tested N-95 mask, higher level respiratory protective devices may be recommended depending of the protocol risk assessment).

The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding biohazardous agents, the tasks that involve handling or exposure to biohazards, the type of required personal protective equipment, and demonstrate proficiency in utilizing this equipment.

Lab staff must receive annual updates or additional training when procedures or hazards change.

Protective laboratory coats, gowns, smocks, or uniforms designated for laboratory use must be worn while working with hazardous materials. Remove protective clothing before leaving for non-laboratory areas. Do not take laboratory clothing home for washing.

Eye and face protection (goggles, face shield or other splatter guard) is used for anticipated splashes or sprays of infectious or other hazardous materials when the microorganisms must be handled outside the Biosafety Cabinet or containment device.

Persons who wear contact lenses in laboratories should also wear eye protection.

Latex exam gloves, synthetic rubber, nitrile, vinyl, or neoprene also provide acceptable barrier protection against biological hazards. Nitrile glove are preferred as they protect against bio-agents, chemical exposure\*, and reduce the potential for allergic reaction. \*Refer to glove selection chart if chemicals will be used:

<http://www.ansellpro.com/download/Ansell_8thEditionChemicalResistanceGuide.pdf>

* Gloves must be worn to protect hands from exposure to hazardous materials. Glove selection should be based on an appropriate risk assessment.
* Change gloves when contaminated or if glove integrity is compromised. Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory. Do not wash or reuse disposable gloves. Dispose used gloves with other contaminated laboratory waste.
* Gloves must not be worn outside the laboratory.

Respirator type is determined by risk assessment and/or REM recommendation. Lab personnel intending to use/wear a respirator mask must participate in the Biological Exposure Occupational Health Program and be trained and fit-tested by REM.

## Section 6 – Biosafety Cabinets and Engineering Controls

All procedures involving the manipulation of infectious materials that may generate an aerosol will be conducted within a Class II Biosafety Cabinet (BSC), with appropriate personal protective equipment, physical containment devices, or other physical containment devices. Aerosols may include pipetting, centrifuging, grinding, blending, shaking, mixing, sonicating, opening containers of infectious materials, inoculating animals, and harvesting infected tissues from animals or eggs.

Infectious agents will be centrifuged inside a BSC or, if in the open laboratory, by using sealed rotor heads or centrifuge safety cups. Vacuum lines should be protected with liquid disinfectant traps and inline HEPA filters.

BSCs must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. BSCs should be located away from doors, windows that can be opened, heavily traveled laboratory areas, and other possible airflow disruptions. REM will offer guidance.

**Section 7 – Biohazard Exposure Occupational Health Program and Exposure**

The Purdue University Biological Exposure Occupational Health Program provides awareness training and/or review, handling information, and medical oversight to anyone at Purdue University working with a Risk Group 2 or higher biological agent (BSL 2 or higher laboratory). Program participation is offered at no charge. Participation includes a risk assessment, agent specific exposure awareness review, and a medical assessment. Individual risk assessments and exposure potentials will be reviewed by medical personnel to determine if vaccinations, serum testing, or pre -exposure baseline sample collection is warranted. When necessary, any post exposure accident information will be available as well.

Incidents that may result in exposure to infectious materials must be reported to the laboratory supervisor, the University Biosafety Officer, and a First Report of Injury must be submitted as soon as possible. Medical evaluation, surveillance, and treatment will be provided.

## Section 8 – Sharps

Purdue Universities Sharps and Infectious Waste Handling procedure will be followed: <https://www.purdue.edu/ehps/rem/documents/programs/sharps.pdf>

Sharps are items that are capable of puncturing, cutting, or abrading the skin: glass and plastic pipettes, broken glass, test tubes, petri dishes, razor blades, needles, syringe with needle. Careful management of needles and other sharps are of primary importance. Needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal. Lab staff that routinely works with sharps and handle sharps waste should use appropriate personal protective equipment, tools, barrier protection, or engineering controls to protect themselves.

**Section 9 - Spill Decontamination**

Spill contingencies must be planned in advance. For example, what supplies and equipment should you maintain in your area to assist you in the event of an accidental spill, e.g., personal protective equipment, disinfecting solutions, spill control materials.

**Risk Group 2 Biohazards Spills:**

Evacuate the room immediately, close doors, remove all contaminated clothing, and decontaminate body surfaces. Contact REM for decontamination instructions.

Allow enough time (at least 30 minutes) for droplets to settle and aerosols to be reduced by the ventilation system before entering.

Don protective clothing and approved respiratory protective equipment.

Decontaminate the spill with an appropriate disinfectant (*e.g.*, 1:10 solution of household bleach in water).

Decontaminate and dispose of contaminated items.

Following cleanup, responders should wash or shower with a germicidal soap.

**Spills inside the Biosafety Cabinet**

Initiate cleanup at once, while the cabinet continues to operate, using an appropriate disinfectant.

Prevent the generation and escape of aerosols and contaminants from the cabinet during decontamination.

Biosafety cabinet decontamination is arranged by REM.

**Spills/Exposure Reporting Procedures for rDNA/Synthetic Nucleic Acid Molecules**

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, requires notification of any spill or accident involving recombinant DNA research that leads to personal injury or illness or to a breach of containment. Examples might include skin punctures with needles containing recombinant DNA, the escape or improper disposition of a transgenic animal, or spills of high-risk recombinant materials occurring outside of a biosafety cabinet. Report these and biohazard spills and accidents to REM (Biosafety Officer) as soon as possible. Note: Minor spills of low-risk agents not involving a breach of containment that were properly cleaned and decontaminated generally do not need to be reported.

## Section 10 – Decontamination

Laboratory wastes will be decontaminated by autoclave, chemical disinfection, incineration, or other validated decontamination method.

Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with 10% bleach solution or 70% ethanol or other appropriate disinfectant.

Decontaminate all cultures, stocks, and other potentially infectious materials before disposal.

Materials to be decontaminated outside of the immediate laboratory must be placed in an autoclavable biohazard bag and kept secured until decontaminated.

Equipment must be decontaminated before repair, maintenance, or removal from the laboratory.

Decontaminate all spills, equipment, counters, and other surfaces. A 10% bleach solution or 70% ethanol can be used to disinfect and a strong detergent and water rinse may remove most drug residues. Repeating the cleaning steps will provide addition drug removal.

Decontamination materials need to be available in case of a spill during transportation.

## Section 11 – Medical Emergency

**Life Threatening Emergency, After Hours, Weekends And Holidays: Dial** **911**.

All employees, whether undergrad, grad, part-time or full-time must go to IU Health Arnett Occupational Health Center, Unity Healthcare’s Regional Occupational Care Center (ROCC), or one of the emergency rooms (if emergency room is required). Purdue University Student Health (PUSH) and the Center for Healthy Living should not to be used for ANY employee injury. Report the incident to the Biosafety Officer as soon as possible.

Immediately report injury to supervisor and complete the First Report of Injury. <https://www.purdue.edu/ehps/rem/froi/ai.html>

## Section 12 – Waste Disposal Procedures

Biological waste must be managed separately from chemical waste. The most common example where chemical waste is mistaken for biological waste is agarose gel contaminated with ethidium bromide or heavy metals (i.e. arsenic, chromium). This type of material should always be managed as chemical waste. When both chemical and biological waste types exist, the biological agent(s) should be treated first. Once the biological agents have been deactivated by either autoclave or chemical disinfection, the remaining chemical waste should be submitted on a Hazardous Materials Pickup Request Form: <https://www.purdue.edu/ehps/rem/documents/forms/biohaz.pdf>

**Section 13 – Sharing Biological Agents or Material and Lab Security**

**Sharing Biological Agents**

Sharing of bio-agents or materials with colleagues promotes and facilitates research, but doing so without institutional oversight could result in safety and regulatory problems. Certain biohazardous agents are closely regulated by the Department of Commerce, Centers for Disease Control, the Animal Plant Health Inspection Service, National Institutes of Health, as well as Purdue University.

It is important that the IBC be made aware of bio-agent sharing prior to the transfer. The IBC will check protocol approvals (IBC, PACUC, and IRB), material transfer agreements, initiate protocol amendments, review bio-agent related training, and discuss specific handling procedures, i.e., labeling, packaging, and shipping. Notifiable bio-agents and materials include:

* Risk Group 2 or above biohazardous agents;
* Human cell lines, unfixed blood, tissue, or fluids; and
* Recombinant or synthetic nucleic acid molecules.

**Laboratory Security**

All laboratory personnel have a responsibility to protect university property from misuse and theft of hazardous materials, particularly those that could threaten human health. At a minimum, the following security measures should be employed in all campus laboratories:

* The laboratory door must remain locked when not occupied; even for short periods of time.
* Always feel free to question anyone that enters the lab that you do not know and ask to see identification if necessary.
* If you see anything suspicious or someone displays suspicious behavior, immediately report it to the Purdue Police Department by dialing 911 (emergency) or (765) 494-8221 (non-emergency).
* Any sensitive information or particularly hazardous biological agents should not be stored out in the open where anyone can readily have access to them. These types of materials must be stored in a secure location and lab personnel must be present when these materials are in use.

## Section 14 – Documentation of Training (signature of all users is required)

* Prior to conducting any work in the BSL2 laboratory, designated personnel must provide training to his/her laboratory personnel specific to the hazards involved in working with this substance, work area decontamination, and emergency procedures.
* The Principal Investigator must provide his/her laboratory personnel with a copy of this SOP and a copy of the Safety Data Sheet provided by the manufacturer.
* The Principal Investigator must ensure that his/her laboratory personnel have attended appropriate laboratory safety training or refresher training annually.

## Section 15 – Institutional Biosafety Committee

If your IBC related research expands or changes beyond the current protocol description, an amendment describing the changes must be submitted to the Biosafety Officer. For example, if new biohazardous agents are to be added, changes in lab staff, collaborations with other labs, and/or processes that require higher containment. IBC form 2A: <http://www.purdue.edu/research/regulatory-affairs/biosafety-and-rdna/forms.php>

**I have read and understand the content of this SOP:**

| **Name** | **Signature** | **Date** |
| --- | --- | --- |
| Click here to enter text. |  | Click here to enter a date. |
| Click here to enter text. |  | Click here to enter a date. |
| Click here to enter text. |  | Click here to enter a date. |
| Click here to enter text. |  | Click here to enter a date. |
| Click here to enter text. |  | Click here to enter a date. |
| Click here to enter text. |  | Click here to enter a date. |
| Click here to enter text. |  | Click here to enter a date. |
| Click here to enter text. |  | Click here to enter a date. |