



Biological Safety Manual

Revised: July 3, 2024

**PURDUE UNIVERSITY
Biological Safety Manual**

Laboratory Specific Biosafety Plan

This is the Biosafety Plan specific to the following areas:

Building(s): _____

Room Number(s): _____

Principal Investigator (Supervisor): _____

Department: _____

Revised (*Must be reviewed at least annually.*): _____

Important Telephone Numbers:

1. 911 for All Emergencies
2. 765-494-8221 Purdue Police Department (Non-Emergency Line)
3. 765-494-6919 Purdue Fire Department (Non-Emergency Line)
4. 765-494-6371 Purdue EHS (Do Not Use for an Emergency)

All laboratories that utilize biohazardous materials must maintain a work-area specific biosafety Plan which conforms to the requirements of the Centers for Disease Control Biosafety in Microbiological and Biomedical Laboratories (BMBL) and the NIH Guidelines for Research Involving Recombinant or synthetic Nucleic Acid Molecules. Purdue University laboratories may use this document as a starting point for creating their work area specific Biosafety Plan. Minimally, this cover page is to be edited for work area specificity (non-West Lafayette laboratories are to place their own emergency, fire, and police telephone numbers in the space above) and the Purdue Biological Safety Manual Awareness Certification Form must be completed for all lab employees. This instruction and information box should remain. This model Biological Safety Manual is the 2020 version; the most current version can be found on the EHS Forms webpage.

Table of Contents

1	Compliance	1
1.1	Laboratory Supervisor Responsibilities.....	1
1.2	Environmental Health and Safety	1
1.3	EHS Researcher's Guide.....	2
1.4	Institutional Biosafety Committee.....	2
2	Occupational Health	3
2.1	Biological Exposure Occupational Health Program.....	3
2.2	Injuries, Illnesses, and Medical Emergency	3
3	Biohazardous Agent Awareness	4
3.1	Training	4
3.2	Online Biosafety Training.....	4
3.3	Biosafety Standard Operating Procedures (SOP).....	4
3.4	Biological Agent Awareness	4
3.5	Biological Risk Assessment.....	5
3.6	Risk Group Classifications (per NIH)	5
3.7	Biosafety Level 1	5
3.8	Biosafety Level 2	6
3.9	Biosafety Level 3	10
3.10	Animal Biosafety Levels	10
4	Bloodborne Pathogen Exposure Control Plan	12
4.1	Training Requirements	12
5	Personal Protective Equipment and Biosafety Equipment	13
5.1	Personal Protective Equipment	13
5.2	Engineering Controls and Safety Equipment	13
5.3	Biological Safety Cabinets	14
5.4	Laminar Flow Clean Benches.....	15
5.5	Safety Showers and Eyewash Stations	16
5.6	Fire Doors	16
5.7	Housekeeping	17
5.8	Shipping	17
5.9	Transporting	18
5.10	Laboratory Security	18
6	Waste Handling	20
6.1	Autoclave	20
6.2	Surface Decontamination	21
6.3	Spills	21
6.4	Sharps Handling Safety.....	22
7	Additional Biosafety Requirements	23
7.1	The Federal Select Agent Program	23
7.2	Dual Use Research of Concern	23
7.3	Recombinant or Synthetic Nucleic Acid Molecules	23
	Appendix A: Biosafety Level 2 (BSL 2) Standard Operation Procedure (SOP)	24
	Appendix B: IBC Forms and Required Safety Training	33
	Appendix C: Summary of Changes	34

1 Compliance

Purdue University is committed to providing a healthy and safe work environment for the campus community. The Biosafety Manual describes the proper use and handling procedures to be followed by faculty, staff, and all other personnel working with biohazards in the laboratory setting.

1.1 Laboratory Supervisor Responsibilities

The Laboratory Supervisor is the individual that is ultimately responsible for the overall laboratory operation and ensuring that the biosafety requirements are followed by all staff members that work in the lab. For most research laboratories, the Principal Investigator (PI) is the Laboratory Supervisor. The PI/Laboratory Supervisor must:

- Understand applicable environmental health and safety rules, including the contents of the Biosafety Manual;
- Identify hazardous conditions or operations in the laboratory and establish Standard Operating Procedures (SOPs) and hazard assessments to effectively control or reduce hazards;
- Ensure that all laboratory personnel that work with hazards receive appropriate training before any work occurs.
- Maintain written documentation of laboratory-specific training (e.g., Personal Protective Equipment (PPE) training);
- Ensure that appropriate PPE (e.g., laboratory coats, gloves, eye protection, etc.) and engineering control equipment (e.g., biological safety cabinets) are made available, in good working order, and being used properly;
- Conduct periodic lab inspections and immediately take steps to abate hazards that may pose a risk to life or safety; and
- Actively enforce all applicable safety procedures and ensure that safety requirements are followed by lab staff and all visitors.

1.2 Environmental Health and Safety

The Environmental Health and Safety (EHS) serves as the environmental health and safety department for Purdue University. EHS's primary role is to manage regulatory compliance with all federal, state, and Purdue regulations involving environmental health and safety issues.

EHS facilitates a number of programs that apply to laboratory safety, including biological safety, chemical safety, laser safety, personal protective equipment program, radiation safety, and the development of standard operating procedures.

EHS also performs numerous safety inspections of facilities throughout the year to monitor compliance with regulatory requirements.

EHS provides services such as training, chemical, biological, and radioactive waste pickups, and safety consultation. More detailed information regarding all of EHS's resources and services can be found on the EHS website.

1.3 EHS Researcher's Guide

EHS has developed a Researcher's Guide. This is a tool that can assist researchers with lab specific compliance for risk assessments, safety training, and emergency contact postings. Visit the EHS website/Researcher's Guide for more detailed information.

1.4 Institutional Biosafety Committee

The primary responsibility of the Purdue University Institutional Biosafety Committee (IBC) is to review and approve research protocols involving the use of recombinant DNA, synthetic nucleic acids, and/or biohazardous agents that present a risk to humans, animals, and plants, on the West Lafayette Campus, Regional Campuses, or related facilities and operations. The IBC is conducted in accordance with the guidance and requirements of the National Institute of Health (NIH), the Centers for Disease Control (CDC), and Purdue University policies. See the Executive Vice President for Research and Partnerships website.

1.4.1 Protocol Application

IBC Form 1A: Use for new applications and triennial renewal.

IBC Form 2A: Amendment

- Changes for approved IBC protocols must be reported by using an amendment form.
- Changes include adding new biological agents, new locations, staff changes, changing the experiment design, adding natural and synthetic nucleic acids, etc. (see Appendix A).

2 Occupational Health

2.1 Biological Exposure Occupational Health Program

The Purdue University Biological Exposure Occupational Health Program provides biohazard awareness, agent specific exposure awareness information, and medical consultation to anyone at Purdue University working with a Risk Group 2 or higher biological agents. Program participation is offered at no charge.

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.

2.2 Injuries, Illnesses, and Medical Emergency

Employees must notify their Laboratory Supervisor of all injuries and illnesses regardless of the magnitude. The laboratory supervisor must ensure that a First Report of Injury (FROI) form is completed. Employees should report to a Purdue approved occupational medical provider if medical attention is required.

If the injury is serious and presents an emergency situation, dial 911 and emergency responders (Purdue Fire Department if located on the West Lafayette Campus) will respond and transport the patient to a local hospital emergency room. For more information regarding the First Report of Injury reporting process, visit the EHS website.

Contact the University Biosafety Officer as soon as possible to report any biohazard exposure or related injury.

3 Biohazardous Agent Awareness

3.1 Training

Effective training is crucial to a successful laboratory safety program. Laboratory Supervisors must actively participate in the training process to ensure that all lab employees are effectively trained before any work with hazardous materials occurs. The Principal Investigator must ensure that his/her laboratory personnel have attended appropriate laboratory safety training or refresher training annually.

3.2 Online Biosafety Training

The completion of Collaborative Institutional Training Initiative (CITI) Biosafety Modules is now required for all lab staff associated with an IBC protocol. CITI training is required for rDNA and biohazard use IBC protocols initially for all lab staff initially, new staff as they arrive, and is repeated triennially. This required biosafety training covers infectious agents, lab practices, shipping, and is documented. Directions for accessing this online training are forwarded to all those associated with an applicable IBC protocol by EHS as part of the approval process. Failure to complete the CITI training may result in personnel being suspended from work on the protocol project.

3.3 Biosafety Standard Operating Procedures (SOP)

The Biosafety Level 2 SOP is a compilation of safe lab practices and mitigation steps that need to be applied when working with biohazardous agents or materials. Prior to conducting any work in the BSL2 SOP laboratory, designated personnel must review the BSL2 SOP with laboratory staff. In addition, agent awareness, handling techniques, emergency procedures, decontamination methods, and PPE precautions must be reviewed for the specific biohazardous agent.

The Principal Investigator must provide his/her laboratory personnel with a copy of this BSL2 SOP, maintain a signed copy in the lab's safety file, and a completed signed copy must be sent to EHS to document this safety review. See Appendix A.

3.4 Biological Agent Awareness

EHS supplies specific agent risk assessments for Risk Group 2 biological agents. These must be reviewed 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 are included.

All laboratory personnel, 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 biohazardous agents.

Lab personnel must receive annual updates or additional training when 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.

3.5 Biological Risk Assessment

A biological 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 lab acquired infection, and the probable consequences of such an infection.

The information identified by a risk assessment will provide a guide for the selection of appropriate biosafety levels and microbiological practices, safety equipment, and facility safeguards that can prevent lab acquired infections.

3.6 Risk Group Classifications (per NIH)

Risk Group 1 (RG1)	Agents that are not associated with disease in healthy adult humans
Risk Group 2 (RG2)	Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are <i>often</i> available
Risk Group 3 (RG3)	Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions <i>may be</i> available (high individual risk but low community risk)
Risk Group 4 (RG4)	Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available.

3.7 Biosafety Level 1

Biosafety Level 1 is suitable for work involving well-characterized agents not known to consistently cause disease in immunocompetent adult humans, and present minimal potential hazard to laboratory personnel and the environment. BSL1 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.

3.8 Biosafety Level 2

Biosafety Level 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 infectious aerosols or splashes may be created are conducted in BSCs or other physical containment equipment.

The following standard and special practices, safety equipment, and facility requirements apply to BSL-2.

A. Standard Microbiological Practices

1. The laboratory supervisor must enforce the institutional policies that control access to the laboratory.
2. Persons must wash their hands after working with potentially hazardous materials and before leaving the laboratory.
3. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption must not be permitted in laboratory areas. Food must be stored outside the laboratory area in cabinets or refrigerators designated and used for this purpose.
4. Mouth pipetting is prohibited; mechanical pipetting devices must be used.
5. Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented. Whenever practical, laboratory supervisors should adopt improved engineering and work practice controls that reduce risk of sharps injuries. Precautions, including those listed below, must always be taken with sharp items. These include:
 - a. 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.
 - b. Used disposable needles and syringes must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal.
 - c. Non-disposable sharps must be placed in a hard walled container for transport to a processing area for decontamination, preferably by autoclaving.
 - d. Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps. Plastic ware should be substituted for glassware whenever possible.
6. Perform all procedures to minimize the creation of splashes and/or aerosols.

7. Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant.
8. Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method. Depending on where the decontamination will be performed, the following methods should be used prior to transport:
 - a. Materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof container and secured for transport.
 - b. Materials to be removed from the facility for decontamination must be packed in accordance with applicable local, state, and federal regulations.
9. A sign incorporating the universal biohazard symbol must be posted at the entrance to the laboratory when infectious agents are present. Posted information must include: the laboratory's biosafety level, the supervisor's name (or other responsible personnel), telephone number, and required procedures for entering and exiting the laboratory.
10. An effective integrated pest management program is required.
11. The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. Personnel must receive annual updates or additional training when procedural or policy changes occur. Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, 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.

B. Special Practices

1. All persons entering the laboratory must be advised of the potential hazards and meet specific entry/exit requirements.
2. Laboratory personnel must be provided medical surveillance, as appropriate, and offered available immunizations for agents handled or potentially present in the laboratory.
3. Each institution should consider the need for collection and storage of serum samples from at-risk personnel.
4. A laboratory-specific biosafety manual must be prepared and adopted as policy. The biosafety manual must be available and accessible.
5. The laboratory supervisor must ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with BSL-2 agents.
6. Potentially infectious materials must be placed in a durable, leak proof container during collection, handling, processing, storage, or transport within a facility.
7. Laboratory equipment should be routinely decontaminated, as well as, after spills, splashes, or other potential contamination.

- a. Spills involving infectious materials must be contained, decontaminated, and cleaned up by staff properly trained and equipped to work with infectious material.
 - b. Equipment must be decontaminated before repair, maintenance, or removal from the laboratory.
 8. Incidents that may result in exposure to infectious materials must be immediately evaluated and treated according to procedures described in the laboratory biosafety manual. All such incidents must be reported to the laboratory supervisor. Medical evaluation, surveillance, and treatment should be provided and appropriate records maintained.
 9. Animal and plants not associated with the work being performed must not be permitted in the laboratory.
 10. All procedures involving the manipulation of infectious materials that may generate an aerosol should be conducted within a BSC or other physical containment devices.
- C. Safety Equipment (Primary Barriers and Personal Protective Equipment)
1. Properly maintained BSCs, other appropriate personal protective equipment, or other physical containment devices must be used whenever:
 - a. Procedures with a potential for creating infectious aerosols or splashes are conducted. These may include pipetting, centrifuging, grinding, blending, shaking, mixing, sonicating, opening containers of infectious materials, inoculating animals intranasally, and harvesting infected tissues from animals or eggs.
 - b. High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory using sealed rotor heads or centrifuge safety cups.
 2. 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, e.g., cafeteria, library, and administrative offices). Dispose of protective clothing appropriately, or deposit it for laundering by the institution. It is recommended that laboratory clothing not be taken home.
 3. Eye and face protection (goggles, mask, 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 BSC or containment device. Eye and face protection must be disposed of with other contaminated laboratory waste or decontaminated before reuse. Persons who wear contact lenses in laboratories should also wear eye protection.
 4. Gloves must be worn to protect hands from exposure to hazardous materials. Glove selection should be based on an appropriate risk assessment. Alternatives to latex gloves should be available. Gloves must not be worn outside the laboratory. In addition, BSL-2 laboratory workers should:
 - a. Change gloves when contaminated, glove integrity is compromised, or when otherwise necessary.

- b. Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory.
 - c. Do not wash or reuse disposable gloves. Dispose of used gloves with other contaminated laboratory waste. Hand washing protocols must be rigorously followed.
 5. Eye, face and respiratory protection should be used in rooms containing infected animals as determined by the risk assessment.
- D. Laboratory Facilities (Secondary Barriers)
 1. Laboratory doors should be self-closing and have locks in accordance with the institutional policies.
 2. Laboratories must have a sink for hand washing. The sink may be manually, hands-free, or automatically operated. It should be located near the exit door.
 3. The laboratory should be designed so that it can be easily cleaned and decontaminated. Carpets and rugs in laboratories are not permitted.
 4. Laboratory furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment should be accessible for cleaning.
 - a. Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
 - b. Chairs used in laboratory work must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.
 5. Laboratory windows that open to the exterior are not recommended. However, if a laboratory does have windows that open to the exterior, they must be fitted with screens.
 6. 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.
 7. Vacuum lines should be protected with liquid disinfectant traps.
 8. An eyewash station must be readily available.
 9. There are no specific requirements for ventilation systems. However, planning of new facilities should consider mechanical ventilation systems that provide an inward flow of air without recirculation to spaces outside of the laboratory.
 10. HEPA filtered exhaust air from a Class II BSC can be safely recirculation back into the laboratory environment if the cabinet is tested and certified at least annually and operated according to manufacturer's recommendations. BSCs can also be connected to the laboratory exhaust system by either a thimble (canopy) connection or directly exhausted to the outside through a hard connection. Provisions to assure proper safety cabinet performance and air system operation must be verified.
 11. A method for decontaminating all laboratory wastes should be available in the facility (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method).

3.9 Biosafety Level 3

(Labs in this level will need to draft a specific Biosafety Plan)

Biosafety Level 3 is applicable to clinical, diagnostic, teaching, research, or production facilities where work is performed with indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure. Laboratory personnel must receive specific training in handling pathogenic and potentially lethal agents, and must be supervised by scientists competent in handling infectious agents and associated procedures.

All procedures involving the manipulation of infectious materials must be conducted within BSCs or other physical containment devices. A BSL-3 laboratory has special engineering and design features.

3.10 Animal Biosafety Levels

3.10.1 Animal Biosafety Level 1

Animal Biosafety Level 1 is suitable for work with animals involving well-characterized agents that are not known to cause disease in immunocompetent adult humans, and present minimal potential hazard to personnel and the environment.

ABSL facilities should be separated from the general traffic patterns of the building and restricted as appropriate. Special containment equipment or facility design may be required as determined by appropriate risk assessment. Personnel must have specific training in animal facility procedures and must be supervised by an individual with adequate knowledge of potential hazards and experimental animal procedures.

3.10.2 Animal Biosafety Level 2

Animal Biosafety Level 2 builds upon the practices, procedures, containment equipment, and facility requirements of ABSL1. ABSL2 is suitable for work involving laboratory animals infected with agents associated with human disease and pose moderate hazards to personnel and the environment. It also addresses hazards from ingestion as well as from percutaneous and mucous membrane exposure.

ABSL2 requires that: 1) access to the animal facility is restricted; 2) personnel must have specific training in animal facility procedures, the handling of infected animals and the manipulation of pathogenic agents; 3) personnel must be supervised by individuals with adequate knowledge of potential hazards, microbiological agents, animal manipulations and husbandry procedures; and 4) BSCs or other physical containment equipment is used when procedures involve the manipulation of infectious materials, or where aerosols or splashes may be created.

Appropriate personal protective equipment must be utilized to reduce exposure to infectious agents, animals, and contaminated equipment. Implementation of employee occupational health programs should be considered. **Search:** Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition.

4 Bloodborne Pathogen Exposure Control Plan

Bloodborne Pathogens are microorganisms that are present in human blood and can cause disease in humans. These disease causing organisms can be found in all body fluids, unfixed tissue, cell lines, and in situations where it is difficult or impossible to differentiate between body fluids and other materials. Annual training and an IBC protocol is required to work with these materials.

4.1 Training Requirements

- Training must take place within 10 days of employment and before there is any blood exposure.
- Training must be conducted by an approved designated trainer or during a monthly scheduled EHS training session.
- Training must be conducted annually.
- Training must contain certain elements as prescribed below in part II section B of the Purdue Bloodborne Pathogens Exposure Control Plan.
- Training documentation, Hepatitis B vaccination rosters, and health release authorization forms must be sent to Environmental Health, EHS/HAMP.
- Employees completing this training will need to complete the Training and Information Certification.

More detail regarding Bloodborne Pathogens can be found in the EHS Compliance Programs.

5 Personal Protective Equipment and Biosafety Equipment

5.1 Personal Protective Equipment

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 (PPE), and demonstrate proficiency in utilizing this equipment.

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

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 or higher level respiratory protective device may be recommended depending of the protocol risk assessment).

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 EHS.

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) are 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 gloves also provide acceptable barrier protection against biological hazards. Nitrile gloves are preferred as they protect against bio-agents, chemical exposure, and reduce the potential for allergic reaction.

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.

5.2 Engineering Controls and Safety Equipment

Laboratory safety controls include engineering controls, administrative controls, and PPE. Elements of these three categories should be used in a layered approach to minimize employee

exposure to hazards. There are four primary routes of exposure in which biohazardous substances can enter the body: inhalation, absorption, ingestion, and injection. Of these, the most likely routes of exposure in the bio-laboratory are by inhalation and/or injection. It is critical that protective measures are in place for each of these exposure routes.

5.3 Biological Safety Cabinets

Biological Safety Cabinets (BSCs) are the primary means of containment for working safely with infectious agents. BSCs are designed to provide personnel, environmental and product protection. HEPA filters remove the particle sizes of 0.3 μm with an efficiency of at least 99.97%. Bacteria, spores and viruses are removed from the air by these filters.

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 generation may result from pipetting, centrifuging, grinding, blending, shaking, mixing, sonicating, opening containers of infectious materials, inoculating animals, and harvesting infected tissues from animals or eggs.

Centrifuging infectious agents must be done inside a BSC or, if in the open laboratory, by using sealed rotor heads or centrifuge safety cups.

Vacuum lines used in a BSC must 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.

Applications that involve the use of chemicals should be conducted in chemical fume hoods.

EHS arranges annual certifications and any repair work.

Consult EHS prior to purchasing, installing, or moving a BSC.

EHS must be contacted for any problems.

Biological Safety Cabinet



5.4 Laminar Flow Clean Benches

A laminar flow clean bench (LFCB) is an enclosed bench designed to prevent contamination of semiconductor wafers, non-biohazardous samples, or any particle sensitive device. Air is drawn through a HEPA filter and blown in a very smooth, laminar flow towards the user. Therefore it is critical that absolutely no hazardous chemicals, infectious and/or radioactive materials ever be used in a laminar flow clean bench, as the vapors are blown directly towards the user. Applications that involve the use of chemicals should be conducted in chemical fume hoods.

EHS arranges annual certifications and any repair work.

Consult EHS prior to purchasing, installing, or moving a LFCB.

EHS must be contacted for any problems.

Laminar Flow Clean Bench



5.5 Safety Showers and Eyewash Stations

All eyewash stations must be flushed by laboratory personnel on a weekly basis to ensure proper working order. This will keep the system free of sediment, prevent bacterial growth, and assure proper performance.

EHS performs annual inspections of all campus safety shower and eyewash stations. This inspection evaluates the basic mechanical functionality of each station. Any deficiencies are repaired either by EHS staff or by Administrative Operations maintenance staff.

If the safety shower or eye wash unit becomes inoperable, notify your building deputy immediately.

5.6 Fire Doors

Many laboratories may contain fire doors as part of the building design. These doors are an important element of the fire containment system and should remain closed unless they are on a magnetic self-closure or other automated self-closing system.

Never disable an automatic door closure device (e.g., placing a block under the door).

If you are unsure of whether a door is fire rated or not, contact EHS at 765-494-6371 and a staff member will come to the area to evaluate the specific door in question.

5.7 Housekeeping

Housekeeping is an important element to a laboratory safety program. A clean, well-maintained lab improves safety by preventing accidents and can enhance the overall efficiency of the work being performed. The following laboratory housekeeping guidelines should be followed:

- All doorways and hallways must be free of obstructions to allow clear visibility and exit. The laboratory should be uncluttered without excessive storage of materials that could cause or support a fire (e.g., paper, cardboard, flammable liquids, etc.).
- Fire protection sprinklers must be unobstructed; a minimum of 18 inches of clearance is required below the sprinkler head. If the laboratory does not have fire protection sprinklers, there must be a minimum of 24 inches of clearance below the ceiling.
- Do not store items that block fire extinguishers or eyewash and safety shower stations.
- Do not store items in front of electrical boxes/panels in the lab.
- A routine cleaning schedule should be established. All work surfaces should be kept as clean as possible. All potentially biohazard contaminated work area surfaces (e.g., biosafety cabinet interior, bench tops) should be decontaminated before and after lab work.
- For operations where spills and contamination are likely (e.g., agarose gel electrophoresis/ethidium bromide applications), cover work spaces with a bench paper or liner. The soiled bench paper should be changed on a routine basis or as needed.
- Do not allow materials to accumulate in Biosafety Cabinets or Chemical fume hoods. Remove used tissues, foil, gloves, or other unnecessary objects immediately after use. The safety of the workspace and the hood ventilation may be compromised when excessive supplies and materials are kept in these cabinets/hoods.
- Ensure that all waste (e.g., trash, biohazardous, chemically contaminated waste, etc.) is placed in the appropriate containers. Do not overfill waste containers.
- All equipment should be cleaned and returned to storage after each use.
- Equipment should be stored in a safe and orderly manner that prevents it from falling.
- Chemical containers must be clean, properly labeled, and returned to storage upon completion or usage. Avoid storing liquids above eye level on shelves and inside cabinets.
- Do not store heavy or frequently used items on top shelves. Locate items used daily close to the work area.

5.8 Shipping

The use of hazardous materials is an integral part of research at Purdue University. At times, it is necessary to ship these materials to a colleague, another research facility, back to the manufacturer, or to a field research site. Hazardous materials may include items such as:

- Laboratory chemicals (including research samples)
- Dry ice

- Radioactive materials
- Compressed gases
- Biological agents
- Equipment or instruments that contain hazardous materials
- Lithium batteries and other rechargeable batteries

When hazardous materials are offered for transport by a commercial carrier like FedEx or UPS, the shipment becomes regulated by the U.S. Department of Transportation (USDOT) and/or international agencies (IATA, ICAO). To comply with shipping regulations, hazardous materials must be properly classified, packaged, documented, and handled by trained employees. Failure to meet these requirements may result in delays, loss of research samples, and potential regulatory fines.

EHS can assist by either providing shipment services, or if necessary, training personnel on the proper shipping procedures for regulated hazardous materials. EHS does not charge for shipment preparation or training services. However, the researcher is responsible for the cost of proper packaging materials, dry ice (if applicable), and shipping costs.

5.9 Transporting

Transport biohazardous materials between labs in a properly labeled sealed container inside a second closed container to minimize the risk of breakage. The secondary container should be secured to the vehicle to ensure movement does not occur during transportation. Carry decontamination materials in the event of a spill.

5.10 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.

The laboratory door must remain locked when not occupied; even for short periods of time.

Always feel free to question anyone that you do not know who enters the lab 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.

5.10.1 Non-Laboratory Personnel / Support Staff

Support staff (e.g., custodians, maintenance workers) and visitors often must enter laboratories to perform routine tasks. When these individuals are present in the laboratory, all work with biohazardous agents must stop.

Minimum PPE requirements for entering a BSL2 laboratory includes eye protection and a lab coat. If additional PPE is required or if other unique safety requirements must be followed, it is the lab personnel's responsibility to notify support staff and/or visitors of the additional requirements.

6 Waste Handling

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

6.1 Autoclave

Cycle	Materials	Description
Gravity or "fast exhaust"	Dry goods, glassware, etc.	This cycle charges the chamber with steam and holds it at a set pressure and temperature for a set period of time. At the end of the cycle, a valve opens and the chamber rapidly returns to atmospheric pressure. Drying time may also be added to the cycle.
Liquid or "slow exhaust"	Liquids	This cycle prevents sterilized liquids from boiling. Steam is exhausted slowly at the end of the cycle, allowing the liquids (which will be super-heated) to cool.

Temperature: Sterilizing cycle temperature must be at least 250°F (121°C).

Time: The sterilizing cycle must be at least 30 minutes (45 to 60 minutes for infectious waste).



6.2 Surface Decontamination

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 additional drug removal.

6.3 Spills

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.

6.3.1 Risk Group 2 Biohazards Spills:

- Evacuate the room immediately, close doors, remove all contaminated clothing, and decontaminate body surfaces. Contact EHS 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 (10% bleach solution or 70% ethanol or other appropriate disinfectant).
- Decontaminate and dispose of contaminated items.
- Following cleanup, responders should wash or shower with a germicidal soap.

6.3.2 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 EHS.

6.3.3 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 EHS (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.

6.4 Sharps Handling Safety

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.

Clean, uncontaminated broken glassware and plastic sharps should be placed in a corrugated cardboard box or other strong disposable container. Do not exceed 20 pounds.

When ready for disposal, the box should be taped shut and prominently labeled as “Sharp Objects/Glass – Discard” or similar wording.

Contact your Physical Facilities Building Services department for specific non-hazardous waste disposal instructions. More detail regarding sharps, including biologically contaminated sharps, can be found in the EHS Sharps and Infectious Waste Handling and Disposal Guidelines.

7 Additional Biosafety Requirements

7.1 The Federal Select Agent Program

The Federal Select Agent Program is jointly comprised of the Centers for Disease Control and Prevention/Division of Select Agents and Toxins and the Animal and Plant Health Inspection Services/ Agriculture Select Agent Services. The Federal Select Agent Program oversees the possession, use and transfer of biological select agents and toxins, which have the potential to pose a severe threat to public, animal or plant health or to animal or plant products. **Search:** CDC Select Agents

7.2 Dual Use Research of Concern

Dual use research of concern (DURC) is life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misused to pose a significant threat with broad consequences to public health and safety, agricultural crops and other plants, animals, the environment, or national security. **Search:** Dual Use Research of Concern

7.3 Recombinant or Synthetic Nucleic Acid Molecules

NIH Guidelines defines recombinant and synthetic nucleic acid molecules as: (i) molecules that a) are constructed by joining nucleic acid molecules and b) can replicate in a living cell (i.e. recombinant nucleic acids); (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (i.e. synthetic nucleic acids); or (iii) molecules that result from the replication of those described in (i) or (ii) above .

Exempt from NIH Guidelines: Those synthetic nucleic acids that: (i) can neither replicate nor generate nucleic acids that can replicate in any living cell (e.g., oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase), and (ii) are not designed to integrate into DNA, and (iii) do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight. **Search:** NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.

Appendix A: Biosafety Level 2 (BSL 2) Standard Operation Procedure (SOP)

The following document is an example of the Biosafety Level 2 (BSL 2) SOP. See EHS's Standard Operating Procedures (SOPs) webpage for an editable Microsoft Word version of this document.



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. <i>(Name and Phone Number)</i>
Location(s) covered by this SOP:	Click here to enter text. <i>(Building/Room Number)</i>
Biohazardous Agents covered by this SOP:	Click here to enter text.

Section 2 – Type of SOP:

Process 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 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 gloves 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 additional 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 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/froj/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.



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.

Appendix B: IBC Forms and Required Safety Training

- IBC Application and amendment forms 1A and 2A.
- Complete the appropriate CITI training modules (www.citiprogram.org). New users will need to set up a user name and password. You will be instructed on which modules to review.
- BSL 2 SOP: Complete, review, send the BSO a copy, and place in a safety binder.
- Bloodborne Pathogens Exposure Control Plan (if handling human cell lines or Human fluids/tissues)
- Monthly Bloodborne Pathogen Training
- Review the biohazard assessment sheet from EHS for your specific bio-agents.
- Personal Protective Equipment Policy: Review
 - PPE Training Documentation: Place in a safety binder.
 - Complete for your lab specific Certification of Hazard Assessment.
- Chemical Hygiene Plan
 - Review and complete Lab-Specific Plan and place it in a safety binder
 - Complete Appendix A: Lab-Specific Training Certification form
- Sharps and Infectious Waste Handling and Disposal Guidelines: Review

Appendix C: Summary of Changes

July 3, 2024

- Added this appendix
- Changed “Radiological and Environmental Management” and “REM” to “Environmental Health and Safety” and “EHS” respectively
- Laboratory Specific Biosafety Plan form: Changed “*This model Biological Safety Manual is the 2020 version; the most current version can be found on the Forms page at www.purdue.edu/rem.*” to “*This model Biological Safety Manual is the 2020 version; the most current version can be found on the EHS Forms webpage.*”
- Changed telephone number format to “###-###-####”
- Removed hyperlinks
- Changed appendices from numbers to letters
- Changed “Purdue Physical Facilities” to “Administrative Operations”
- Revised Appendix B: IBC Forms and Required Safety Training