**THIS IS A TEMPLATE/BASIC STARTING POINT. CUSTOMIZE THIS TEMPLATE WITH INFORMATION PERTINENT TO YOUR SETUP AND THE PROCEDURE YOU WILL BE USING/YOUR GROUP’S PERSONAL USE.**

STANDARD OPERATING PROCEDURE

Use this form to document the Health and Safety information associated with the procedure.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Procedure Title** | | SOP for work with biohazardous materials | | | | | | |
|  | |  | | | | | | |
| **Dept** |  | |  | **Bldg/Rm** |  |  | **Supervisor** |  |

**Procedure Overview** (a brief description of the project)

The purpose of this Standard Operating Procedure (SOP) is to outline procedures that should be followed when performing work with (identify biohazardous material(s)). Provide a description of the specific work performed in the laboratory.

Biohazardous materials are those materials of biological origin that could potentially cause harm to humans, domestic, or wild animals, or plants. Examples include recombinant or synthetic nucleic acid molecules, transgenic animals or plants, human, animal, or plant pathogens, biological toxins (such as tetanus toxin), human blood, and certain human body fluids, and human or primate cell cultures.

**Health and safety information for materials used (**briefly describe the hazards associated with the materials and/or equipment **OR** document your hazard assessment in Section I)

Section III Hazard Assessment: Considerations, provides considerations to help facilitate a biological risk assessment.

Consider health and safety concerns related to additional materials (such as chemicals), methods, or equipment associated with your protocol(s). Include as part of this SOP or create a separate SOP to address the hazards associated with the use of these materials, methods, equipment, etc.

**Hazard Control Measures**

Please select which type of lab coat, eye protection, and hand protection will be used (Lab coat, eye and hand protection, and closed toe/heel shoes must be selected as required by Section D of the ISU Laboratory Safety Manual.) Deviation from this policy should be noted and justified along with a risk assessment.

All work with biological material that contains human pathogens, human or non-human primate derived tissue culture, or as required by a USDA permit must be performed in a BSL2 laboratory. This includes a room suitable for work with biohazardous materials and equipped with a certified Class II Biosafety Cabinet (BSC).

|  |  |  |  |  |  |  |  |
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|  | Latex gloves |  | Insulated gloves |  | Face Shield |  | Respirator |
|  | Nitrile gloves |  | Safety glasses |  | Lab Coat |  | Fume hood |
|  | Neoprene gloves |  | Vented goggles |  | Apron |  | Biosafety cabinet |
|  | Vinyl gloves |  | Splash goggles |  | Dust mask |  | Glove box |
|  | Closed Toe/Closed Heel Shoes | | |  | Flame Resistant Lab coat | | |

***Other Control Measures***

The following are examples of control measures that should be considered for work with biohazardous materials. Consider additional health and safety concerns related to additional materials (such as chemicals) or methods associated with your protocol(s). Include additional control measures here or in a separate SOP.

All laboratory staff is informed about the hazards of the biohazardous material before working with this material. Before working with human pathogens, blood, tissues, or cell lines, all applicable safety information must be reviewed and documented. Familiarity with the exposure routes, symptoms, and treatment methods will provide better preparation in the event of exposure to biohazardous materials. (This SOP may or may not serve as part of this training).

Work with biohazardous materials is performed using standard microbiological practices including;

* The laboratory has a door for access control.
* The laboratory is designed so that it can easily be decontaminated.
* Laboratory windows that open to the exterior are fitted with screens.
* Eating, drinking, food storage, handling of contact lenses, applying cosmetics, mouth pipetting, and use of

tobacco products are prohibited in the laboratory.

* Do not store food in freezers, refrigerators, cabinets, or any other areas where biohazardous materials are stored or may be contaminated with biohazardous materials.
* A sign is posted at the entrance to the laboratory when infectious materials are present. A door sign incorporating emergency contacts and hazard information for the lab using the following link: <http://www.ehs.iastate.edu/services/occupational/door-signage>
* Long hair is restrained so that it cannot contact hands, specimens, containers, or equipment.
* Gloves are worn to protect against biohazardous materials, Disposable gloves are disposed of in an appropriate waste receptacle and are not washed or reused. Gloves are not worn outside of the lab. Gloves are changed when contaminated, glove integrity is compromised, or when otherwise necessary.
* All PPE is removed before leaving the laboratory and disposed of or properly stored.
* A sink, soap, and paper towels are available in the lab
* Hands are washed after performing work and before leaving the lab
* An eyewash station is located within the laboratory.
* Work surfaces and equipment are decontaminated after using biohazardous materials.
* Mouth pipetting is prohibited. Mechanical pipetting devices are used.
* Broken glassware is not handled directly. Instead, it is removed using a brush and dustpan, tongs, or forceps
* Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leak-proof container and secured for transport. For infectious materials, the outer surface of the container is disinfected prior to transporting the material.
* An effective pest management program is implemented.
* Animals and plants not associated with the work being performed are not permitted in the laboratory.
* An eyewash station is located within the laboratory.

In addition to standard microbiological practices

Work with biohazardous materials is performed using BSL2 practices including;

* There is authorized access to the laboratory. Lab doors are self-closing and locked when the laboratory is unattended.
* Biosafety cabinets are certified annually and used appropriately.
* Use leak-proof and non-breakable containers for the storage of biohazardous materials.
* Biohazardous materials are placed in durable, leak-proof containers during collection, handling,

storage and transport. Use secondary containment when these materials are transferred through hallways or between buildings. The transport container has a universal biohazard label.

* Keep biohazardous waste containers near the area where work with biohazardous materials is being performed.
* Never overfill waste containers.
* Use extreme caution when working with sharp objects such as needles, razor blades, or broken

glass/ plastic, and dispose of in an appropriate sharps container

* An autoclave is available for decontaminating laboratory waste.
* Furniture is capable of being cleaned and decontaminated.
* Access to the laboratory is limited and doors are always closed to maintain BSL2 containment.
* All waste material is decontaminated prior to disposal.
* Vacuum lines are protected by liquid disinfectant traps and in-line HEPA filters or their equivalent.
* Any experiments of lesser biohazard are demarcated by space or time.
* Open flames are prohibited in the BSC.
* Procedures that generate aerosols are performed in the BSC including pipetting and vortexing.
* Work surfaces and equipment are decontaminated after using biohazardous materials.

All laboratory staff should complete a [Hazard Inventory](https://publications.ehs.iastate.edu/bbp/10/) form for evaluation for enrollment in the Occupational Medicine Program.

All laboratory staff working with biohazardous materials should work under the policies and guidelines established in the EH&S [Biosafety Manual](https://publications.ehs.iastate.edu/bsm/files/assets/common/downloads/publication.pdf?uni=c9ca461aeabe5a5b0eca89c3850e27d0).

The Biosafety Manual outlines appropriate practices, university policies, and regulatory requirements for working safely with biohazardous materials. For a comprehensive overview of the core requirements that must be followed in all laboratories at ISU, please see the [Laboratory Safety Manual.](https://publications.ehs.iastate.edu/labsm/)

All laboratory staff working with human and nonhuman primate derived tissue culture should be enrolled in the Occupational Medicine Program specific to bloodborne pathogens. Participation requires the completion of a [Hazard Inventory](https://publications.ehs.iastate.edu/bbp/10/) form. Participation requires annual Bloodborne Pathogens Exposure Control training and offers personnel the choice of receiving Hepatitis B vaccination.

All laboratory staff working with human-derived tissue culture should work under the policies and guidelines established in the EH&S [Bloodborne Pathogens Manual](https://publications.ehs.iastate.edu/bbp/), which serves as the Exposure Control Plan for Iowa State University.

All laboratory staff working with human pathogens must be given the option of being vaccinated, provided a vaccine is available, and informed of the risks associated with the vaccine.

A sharps policy is implemented.

* Never recap, bend, or break needles
* If necessary to recap a needle, use a mechanical device, such as forceps, to handle the cap
* Handle other sharps such as broken glass/plastic, scalpels, razorblades, broken Pasteur pipets, and
* broken capillary tubes with mechanical devices whenever possible
* Dispose of sharps in appropriate sharps containers
* Avoid the use of sharps or breakable materials and use safer sharps devices whenever possible

See the ISU [SOP Library](https://www.ehs.iastate.edu/research/laboratory/SOPs/library) for applicable Standard Operating Procedures to address additional hazards associated with materials (such as chemicals), methods, equipment, etc. utilized in your laboratory. These SOPs have been provided as a starting point for researchers to develop lab/research-specific SOPs.

See the [Workplace Hazard Assessment for Personnel with Animal Contact](https://www.ehs.iastate.edu/sites/default/files/uploads/forms/AnimalAssessment.pdf) to identify relevant hazards and mitigation strategies related to working with animals in research.

See the [Biosafety Manual](https://publications.ehs.iastate.edu/bsm/files/assets/common/downloads/publication.pdf?uni=c9ca461aeabe5a5b0eca89c3850e27d0) for ways to mitigate hazards related to procedures that create aerosols. All work with biohazardous materials that create aerosols must be performed in the biosafety cabinet if possible.

**Methods**

**Biohazardous Material Specific Procedures**

See attached or Available…

**Basic Biosafety Cabinet (BSC) Procedures**

**BSC Maintenance**

* BSCs must be cleaned and disinfected before and after each use
* All repairs, filter changes, and certifications must be performed by a qualified servicing company, by NSF certified technicians.
* BSCs must be recertified whenever they are moved, repaired, or have the filters changed

**Prior to BSC use**

* Don appropriate Personnel Protective Equipment (See Hazard Control Measures, above)
* Open the BSC sash to the appropriate sash height.
* Turn on the cabinet blower and lights, and check the front and rear air intake grills of the cabinet to make sure they are not obstructed.
* Verify the cabinet is working properly.
* Do not use a BSC that is alarming, this indicates reduced airflow.
* Disinfect the cabinet working surface and walls with appropriate disinfectant, allowing for a minimum 5-minute contact time. If bleach or other corrosive disinfectant is used, wipe the surface and walls with 70% ethanol to remove residual disinfectant that may corrode the stainless-steel surface.
* Allow the blower to operate a minimum of 15 minutes before aseptic manipulations begin in the cabinet.

**Use of BSC**

* Place only necessary materials onto the cabinet work surface. Waste receptacles should be placed inside the BSC
* Disinfect media bottles and supplies with an appropriate disinfectant prior to placing them inside the BSC.
* Active work should flow from clean to contaminated areas across the work surface.
* Avoid rapid arm movements or frequent movement of arms into and out of the BSC.
* Use filtered tips for all manipulations.
* Connect aspiration bottles or suction flasks to an overflow collection flask filled with disinfection and to an inline HEPA filter.
* Do not cover/block air intake grills.
* (As applicable) Disinfect original cultures and liquid waste inside the BSC (see Waste Disposal Procedures, below).
* (As applicable) Collect original cultures and liquid waste inside the BSC to be autoclaved (see Waste Disposal Procedures, below).
* (Include lab-specific procedure(s) for contaminated solids and sharps) Collect contaminated disposable plastic ware, plastic sharps, glass sharps, and metal sharps separately. Items can be removed from the BSC after they have been decontaminated with an appropriate disinfectant or can be placed within a bag or sealed container in the BSC, which is sealed with disinfectant before removal from the BSC (see Waste Disposal Procedures, below).

**Following BSC use**

* Disinfect media bottles and other supplies when removed from the biosafety cabinet.
* Disinfect work surfaces, micropipettes, and pipet aids used with appropriate disinfectant.
* Disinfect the cabinet working surface and walls with an appropriate disinfectant and allow for a minimum 5-minute contact time. If bleach or other corrosive disinfectant is used, wipe the surface and walls with 70% ethanol to remove residual disinfectant that may corrode the stainless-steel surface.
* Leave the BSC running for a minimum of 15 minutes.
* Turn off blowers and lights.
* Decontaminate any additional laboratory surfaces (such as benchtops), as applicable.
* Remove PPE and wash hands with soap and water for a minimum of 20 seconds.

**Disposal and Disinfection**

**General**

* Generated waste should be disposed of as outlined in the [Waste and Recycling Guidelines](https://publications.ehs.iastate.edu/warg/).
* Work surfaces and equipment are decontaminated routinely, and when work is concluded.
* Choosing the appropriate chemical disinfectant depends on the surface or item needing decontamination, as well as the organism requiring inactivation.
* Disinfect or autoclave reusable containers that have been in the biosafety cabinet.
* See the [Biosafety Manual](https://publications.ehs.iastate.edu/bsm/files/assets/common/downloads/publication.pdf?uni=c9ca461aeabe5a5b0eca89c3850e27d0) for more information about disposal and disinfection.
* The ISU [Sharps and Biohazardous Waste Disposal Flowchart](https://www.ehs.iastate.edu/sites/default/files/uploads/publications/factsheets/sharpsflowchart.pdf) is posted in the laboratory.

**Liquid Waste**

* (As applicable) Decontaminate all liquid biohazardous materials by treatment with an appropriate chemical disinfectant for sufficient contact time.
  + Consult the SDS of the disinfectant to determine proper disposal.
  + Remove as liquid chemical waste by submitting a [Waste Removal](https://www.ehs.iastate.edu/services/waste/wasteremoval) request.
* (As applicable) Decontaminate all liquid biohazardous materials by autoclaving.
  + Median containing heat-liable antibiotics can be decontaminated by autoclaving. If the media contains no chemical constituents, the liquid may be disposed of by pouring them down the drain to the sanitary sewer
  + Media containing heat-stable antibiotics can be decontaminated by autoclaving, however, it should be removed as chemical waste by submitting a [Waste Removal](https://www.ehs.iastate.edu/services/waste/wasteremoval) request.

**Disposable Solids**

* Collect all non-sharp, disposable items (such as gloves, plastic ware, Kim wipes, etc.) contaminated with biohazardous materials in leak-proof autoclavable biohazard bags.
* Before decontaminating, place an autoclave indicator tape “X” over the biohazard symbol
* Decontaminate the waste by autoclaving for a minimum of 45 minutes before disposal
* After autoclaving, place the now decontaminated biohazard bag into a dark garbage bag, seal it, and place it in the regular trash.

**Laboratory Sharps-** Use separate containers to collect metal, glass, and plastic sharps

**Metal Sharps**

* Collect all metal sharps contaminated with biohazardous materials in autoclavable, leak-proof, puncture-resistant containers, which have been labeled with the universal biohazard symbol. Decontaminate the containers by autoclaving.
* After autoclaving, label the now decontaminated sharps waste containers with a “Non-Infectious Syringes and Metal Sharps Only” label.
* Collect metal sharps that have never been contaminated with biohazardous materials (e.g., used only with chemicals) in leak-proof, puncture-resistant plastic containers labeled with a “Noninfectious Syringes and Metal Sharps Only” label. Do not autoclave these containers, because they will melt.
* To dispose of metal sharps, submit a [Waste Removal](https://www.ehs.iastate.edu/services/waste/wasteremoval) request. EH&S will only pick up metal sharps waste that has been decontaminated.

**Glass Sharps**

* Collect all glass sharps contaminated with biohazardous materials in autoclavable leak-proof, puncture-resistant containers that have been labeled with the universal biohazard symbol. Decontaminate the containers by autoclaving.
* Collect glass sharps that have been autoclaved or that have never been contaminated with biohazardous materials (used only with chemicals) in a yellow tidy cat container in your laboratory for storage or into the yellow glass disposal bin on your building’s loading dock for disposal. Autoclaving of these containers is not necessary. Call FP&M at (515) 294-5100 for removal when the bin is full.

**Plastic Sharps**

* Collect plastic materials (pipette tips, plastic pipettes) that can poke out of bags and are contaminated with biohazardous materials in autoclavable, leak-proof, puncture-resistant containers which have been labeled with the universal biohazard symbol.
* Decontaminate the containers by autoclaving.
* After autoclaving, place the now decontaminated plastic sharps inside a garbage bag-lined cardboard box, seal, label “Plastic Sharps” and throw into the regular trash dumpster.

**Spill Cleanup Procedures**

**Small spill within the BSC**

* Small spills within the operating BSC can be handled immediately, the blower must remain on.
* Remove any sharp contaminated objects from the spill area using mechanical means, never by hand.
* Cover small spills within the BSC with paper towels and apply an appropriate disinfect starting from the outside working in. Allow appropriate contact time, usually 20 minutes. Collect towels at the edge of the spill and push toward the center and dispose of them in a biohazard bag or receptacle.
* Wipe down the cabinet interior and items inside of the cabinet with a towel dampened with disinfectant.
* Change gloves following decontamination.

**Large spill within the BSC**

* Spills that result in the liquid flowing through the front or rear grill(s) require more extensive decontamination.
* Remove any sharp contaminated objects from the spill area using mechanical means, never by hand.
* Surface decontaminate and remove all items within the cabinet.
* Ensure the drain valve is closed and pour disinfectant solution onto the work surface and through the grille(s) into the drain pan. Allow for appropriate contact time, usually 20 minutes. Attach a hose barb and flexible tube to the drain valve that is long enough to allow the open end of the tube to be submerged in disinfectant within a collection vessel. Empty the drain pan into a collection vessel containing disinfectant. Flush the drain pain with water, remove the drain tube, and close the drain valve.
* Change gloves following decontamination.
* Allow the cabinet to run for at least 10 minutes before resuming use.

Note: Alcohol is not recommended as a disinfectant for large spills, especially within a BSC, because large amounts of alcohol pose an explosion hazard.

**Spills outside of the BSC**

* Remove potentially contaminated clothing and place in a biohazard bag for autoclaving.
* Wash hands and exposed body parts with soap and water.
* Evacuate the laboratory for at least 30 minutes. Post signs if necessary.
* Apply first aid or call 911, if necessary.
* Caution everyone not needed for spill cleanup to stay away from the spill area. Post signs if necessary.
* Don disposable gloves, eye protection, and a lab coat for spills smaller than 100mL. (base on risk assessment). Also, Don an N95 respirator for spills greater than 100mL. (base on risk assessment)
* Remove any sharp contaminated objects from the spill area using mechanical means, never by hand.
* Cover the spill with paper towels and apply an appropriate disinfect starting from the outside working in. Allow for the appropriate contact time, usually 20 minutes. Collect towels at the edge of the spill and push toward the center and dispose of them in a biohazard bag or receptacle.
* Repeat decontamination step. Place disposable materials into biohazard bag. Spray non-disposable items with disinfectant.
* Remove PPE and wash hands thoroughly with soap and water.

**First Aid Procedures (adapt to biohazardous material)**

* Wash the affected area (facial mucous, broken or punctured skin, etc.) immediately with soap and water or in an eye wash for 15 minutes if exposure happened.
* Use First Aid Kit for minor injuries or short-term emergency treatment before getting medical assistance. Call 911 if necessary.
* Remove any contaminated clothing, place in a biohazard bag and decontaminate.
* Inform supervisor and follow up with occupational medicine specialist or appropriate medical care if needed.

**All accidents and injuries occurring at work or in the course of employment must be reported to the employee's supervisor as soon as possible (even if no medical attention is required).**

**Report all incidents and exposures here:**

[**https://www.ehs.iastate.edu/services/occupational/accidents-injuries**](https://www.ehs.iastate.edu/services/occupational/accidents-injuries)

**References**

Biosafety in Microbiology and Biomedical Laboratories, 6th edition

<https://www.cdc.gov/labs/BMBL.html>

ISU Biosafety Manual

<http://www.ehs.iastate.edu/publications/manuals/bsm.pdf>

ISU Bloodborne Pathogens Manual

<https://publications.ehs.iastate.edu/bbp/>

ISU Sharps and Biohazard Waste Procedures Factsheet

<https://www.ehs.iastate.edu/publications/factsheets/sharps.pdf>

ISU Lab Safety Manual

<http://publications.ehs.iastate.edu/labsm/>

OSHA’s Bloodborne Pathogens Standard (29CFR 1910.1030)

<https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030>

Spills of Biohazardous Materials, webpage and associated documents

https://www.ehs.iastate.edu/research/biological/microbial/spill-cleanup

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| **Approved By** |  |  |  | **Date** |  |

(PI or Lab Supervisor)

1. **HAZARD ASSESSMENT**

Use the hierarchy of controls to document the hazards and the corresponding control measure(s) involved in each step of the procedure. See III. Hazard Assessment: Considerations (below)

Consider *elimination or substitution* of hazards, if possible.

***Engineering Control(s):*** items used to isolate the hazard from the user (i.e. fume hood, biosafety cabinet).

***Administrative Control(s****):* policies/programs to limit the exposure to the hazard (i.e. authorizations, designated areas, time restrictions, training).

***Required PPE***: indicate PPE including specific material requirements if applicable (i.e. flame resistant lab coat, type of respirator or cartridge).

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| --- | --- | --- | --- |
| **Hazard** | **Engineering Control(s)** | **Administrative Control(s)** | **Required PPE** |
| **INSERT SPECIFIC HAZARDS/CONTROLS HERE** |  |  |  |
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According to ISU Policy, the minimum PPE that is required while working with laboratory hazards is lab coat or clothing protection, safety glasses or goggles, and fully enclosed shoes. Deviation from this policy should be noted and justified along with a risk assessment.

1. **TRAINING RECORD**

Use the following table to record the training associated with this Standard Operating Procedure.

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| --- | --- | --- | --- |
| **Print Name** | **Signature** | **Trained By** | **Date** |
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1. **HAZARD ASSESSMENT: Considerations**

**Biological Hazard Assessment should include but is not limited to:**

1) Identify/describe biological agent(s) or material(s) utilized in research.

* Infectious microorganism
* Prions
* Genetically-modified agents
* Recombinant or synthetic nucleic acid molecules
* Specimen source and likely organisms.
* Human blood or other potential infectious material covered by the bloodborne pathogen standard
* Select Agent or Toxins
* Risk Group (RG) of biological agent (as defined by NIH Guidelines)
  + RG1- Agents not associated with disease in healthy adult humans
  + RG2- Agents associated with human disease that is rarely serious and for which preventative or therapeutic interventions are often available.
  + RG3- Agents associated with serious or lethal human disease for which preventative or therapeutic interventions may be available.
  + RG4- Agents likely to cause serious or lethal disease in humans. Not utilized at ISU.

2) Identity the hazards associated with the biological agent(s) or materials(s)

* Pathogenicity as measured by capability to infect and cause disease in a susceptible host
* Virulence as measured by severity of disease
* Availability of preventative measures and effective treatments for the disease
* Probable routes of transmission of laboratory infection

The predominant routes of transmission in the laboratory include mucous membrane exposure, parenteral inoculation (needlestick), ingestion, and inhalation of infectious aerosols.

* Reports of laboratory acquired infections
* Infectious dose
* Stability in the environment
* Host range
* Endemic or emerging disease
* Origin or source
* Genetic modification that affects pathogenicity, virulence, susceptibility to treatments or antibiotics, etc.

3) Identify the hazards associated with the procedures or manipulation of biological agent(s) or materials

* Concentration and volume of material to be manipulated
* Use of laboratory animals; consider allergens, bites, scratches, kicks, noise, zoonotic agents, etc.

See [Workplace Hazard Assessment for Personnel with Animal Contact.](https://www.ehs.iastate.edu/sites/default/files/uploads/forms/AnimalAssessment.pdf)

* Use of insect vectors
* Activities that are known or suspected to create aerosols such as (but not limited to); pipetting, shaking containers, vortexing, grinding tissues in blenders, centrifuging, streaking agar plates, blending, sonicating, lyophilizing, or freezing, sterilizing with open flames, operating a flow cytometer.
* Work with human or non-human primate derived tissue culture.
* Disinfectant used for decontamination or inactivation of laboratory equipment and infectious agents.
* Equipment used such as an autoclave or flow cytometer

4) Determine appropriate biosafety level containment and practices for working with the materials based on risk. Regulatory recommendations (USDA, CDC, OSHA) must be adapted. Engineering control(s), administrative controls(s), and required PPE must be tailored to the biohazardous research conducted based on a risk assessment.

5) Revisit the risk assessment and appropriate biosafety level containment and practices regularly and when there are changes to the research which impact the risk(s) associated with the biohazardous research conducted.