U-M Biosafety Manual

SUPPLEMENTS TO THE UNIVERSITY OF MICHIGAN U-M BIOSAFETY MANUAL ARE FOUND IN SECTION 14

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SECTION 1: INTRODUCTION

The University of Michigan (U-M) Biosafety Manual is a resource for information, guidelines, policies, and procedures that will encourage safe research and eliminate, or reduce, the potential for exposure to biohazards. The information presented here also reflects the requirements and guidelines of federal and state regulations. The U-M Biosafety Manual is written to align with the CDC/NIH publication *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) and the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*.

The U-M Biosafety Manual is applicable to all laboratory, research, teaching, and support activities that may involve biohazards. bacteria, biological toxins, viruses, fungi, rickettsia, prions, protozoans, parasites, genetically modified organisms, and recombinant or synthetic nucleic acid molecules. In addition, biohazards include human blood, body fluid, tissues, and cell lines of human origin and certain animal-derived tissues, fluids, and cells.

The most current version of the U-M Biosafety Manual will be maintained on the Environment, Health & Safety (EHS) website. The U-M Biosafety Manual will be reviewed and updated annually by the U-M Biosafety Officer.

The U-M Biosafety Manual should not be considered the only reference to address biological safety. The Principal Investigator (PI) or supervisory personnel **must** conduct and document lab specific biosafety training. Documents are available on the EHS website (Research & Clinical Tab then Biological Tab) to provide instruction and guidance regarding specific practices and procedures conducted in their lab.

The U-M Exposure Control Plan (ECP) applies to all U-M departments whose employees may reasonably anticipate contact with blood or other potentially infectious materials (OPIM) during the performance of their duties. In compliance with the Michigan Occupational Safety and Health Administration (MiOSHA) Bloodborne Infectious Diseases Standard, U-M requires all departments that fall within the scope of this policy to minimize employee risk from exposure and infection by implementing the U-M ECP.

Acknowledgement

PIs and all laboratory personnel active in research within laboratories under their charge **must** agree to comply with the provisions of the U-M Biosafety Manual and to complete both EHS online biosafety training and lab specific biosafety training to address hazard conditions which are specific to the laboratory spaces under their charge. The contents of this manual **must** be reviewed with laboratory personnel, and they **must** be given the opportunity to ask questions or voice concerns regarding their job description and work environment.

U-M Biological Materials Policy Statement

All research with potentially hazardous biological materials **must** be registered with the U-M Institutional Biosafety Committee (IBC). It is the policy of the U-M Institutional Biosafety Committee (IBC) that researchers working with biohazards at the university will adhere to the U-M Biosafety Manual when implementing the IBC-approved biosafety level in their laboratory.

The potentially hazardous biological materials are as follows:

- Recombinant DNA and synthetic nucleic acid molecules (this includes human gene transfer studies)
- Infectious agents
- Biological toxins

- Human-derived tissues, fluids, cells
- Certain animal-derived tissues, fluids, cells
- Federally-regulated Select Agents, experiments with Dual Use Research of Concern potential, and research requiring BSL3 containment

SECTION 2: RISK GROUP CLASSIFICATION

Risk groups are a method used by the National Institutes of Health (NIH) to classify human infectious agents on the basis of hazard. There are four risk groups which are classified according to their relative pathogenicity for healthy adult humans.

Risk Group Definitions

Risk Group 1 (RG1)	Agents are not associated with disease in healthy adult humans.	Well-characterized, minimal potential hazard to lab personnel and environment.
Risk Group 2 (RG2)	Agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.	Moderate hazards to personnel and the environment.
Risk Group 3 (RG3)	Agents are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available.	Indigenous or exotic agents, inhalation route of exposure.
Risk Group 4 (RG4)	Agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available. RG4 agents are not permitted at U-M.	Dangerous and exotic agents, high risk of aerosol-transmission and life-threatening diseases or unknown risk of transmission.

SECTION 3: BIOSAFETY LABORATORY PRACTICES

Standard Microbiological Practices

Standard Microbiological Practices (SMPs) are generally defined as the basic “hygiene” practices that apply to all labs, regardless of containment level, that manipulate microorganisms or any biological materials that contain microorganisms. SMPs serve to minimize the spread of contamination generated through lab processes and to protect both personnel and the environment. The standard microbiological practices listed below apply to all biosafety containment levels.

- The lab supervisor enforces the institutional policies that control safety in and access to the lab.
- The lab supervisor ensures that lab personnel receive appropriate training regarding their duties, potential hazards, manipulations of infectious agents, necessary precautions to minimize exposures, and hazard/exposure evaluation procedures (e.g., physical hazards, splashes, aerosolization) and that appropriate records are maintained. Personnel receive annual updates and additional training when equipment, procedures, or policies change.
- All personnel, and particularly those of reproductive age and/or those having conditions that may predispose them to increased risk for infection (e.g., organ transplant, medical immunosuppressive

agents), are provided information regarding immune competence and susceptibility to infectious agents.

- A sign incorporating the universal biohazard symbol is posted at the entrance to the laboratory when infectious materials are present. Posted information includes: the laboratory's Biosafety Level, the responsible personnel's name and telephone number, PPE requirements, general occupational health requirements, and required procedures for entering and exiting the laboratory.
- Persons **must** wash their hands after working with potentially infectious materials and before leaving the laboratory.
- Eating, drinking, smoking, vaping, handling contact lenses, applying cosmetics, and storing food for human consumption are not permitted in the laboratory. Food is stored outside the lab area.
- Mouth pipetting is strictly prohibited; mechanical pipetting devices **must** be used.
- 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.
- Appropriate gloves are worn, changed when contaminated, not reused, and not worn outside the lab.
- Gloves and other PPE are removed in a manner that minimizes personal contamination and transfer of infectious materials outside of the areas where infectious materials and/or animals are housed or manipulated.
- Non-experimental animals and plants are not permitted in the laboratory.
- An effective integrated pest management program is required.
- Perform all procedures to minimize the creation of splashes and aerosols.
- Long hair is restrained so that it cannot contact hands, specimens, containers, or equipment.
- A biosafety manual is available and accessible.
- Decontaminate work surfaces after completion of work and after any spill of potentially infectious materials. A spill procedure is developed and posted within the laboratory.
- Decontaminate potentially infectious materials before disposal, or dispose in biohazard waste bins collected by vendor (waste is decontaminated by vendor).

SECTION 4: BIOSAFETY LEVELS (BSL) FOR UM LABORATORIES

The following table identifies the agents used, facility requirements, and work practices for each biosafety level. Researchers who utilize multi-room laboratories or animal suites where both BSL-1 and BSL-2 activities are performed must comply with BSL-2 procedures

BIOSAFETY LEVEL	FACILITY REQUIREMENTS	PRACTICES

BSL1
 	
Agent(s) used:
Noninfectious
	• Doors for access control
	• Sink for handwashing
	• Eyewash station readily available in the lab
	• Screens on windows that open to the exterior
	• Lab can be easily cleaned and support anticipated uses. (no carpet, fabric furniture, or porous benchtops)
	• BSCs and primary containment systems are installed and operated in a manner to ensure their effectiveness
		• Standard Microbiological Practices
		• All laboratory-related incidents, injuries, illnesses, and near misses are reported to EHS
		• Special Practices
		  ○ None
		• Personal Protective Equipment
		  ○ Gloves
		  ○ Lab coat while working
		  ○ Protective eyewear

BSL2
 	
Agent(s) used:
Infectious spread via blood or oral/fecal transmission
 	
Includes human blood, human cell lines, toxins, venom, materials from Nonhuman primates
	All BSL1 requirements plus the following:
	• The sink should be located near the exit door
	• Door(s) should be self-closing and lockable
	• Vacuum lines protected
	• Autoclave available or approved alternative decontamination method
	• Laboratories should be under negative pressure or must be neutral pressure
		All BSL1 requirements plus the following:
		• Special Practices:
		  ○ Controlled access
		  ○ Personnel demonstrate proficiency in SMPs & techniques
		  ○ Medical surveillance as appropriate and offered available immunizations
		  ○ Biosafety cabinet or other containment device used for aerosol generating procedures
		  ○ Lab equipment is routinely decontaminated
		  ○ Method of decontamination for lab waste
		• Personal Protective Equipment
		  ○ Face protection for splashes when working outside of a biosafety cabinet or containment device
		  ○ Risk assessment considers respiratory protection.

BSL3 Agent(s) used: Infectious spread via aerosol transmission	All BSL1 and BSL2 requirements plus the following: • Double door entry • Negative air flow • Biosafety cabinet(s) • Hands free sink • Laboratory has sealed penetrations	All BSL1 and BSL2 requirements plus the following: • Enhanced secured access • All work conducted in biosafety cabinet or other containment device • Facility decontamination may be performed • Decontamination practices are routinely verified
BSL4	No work at a BSL4 is conducted at the University of Michigan	

Animal Biosafety Levels

A similar set of four biosafety levels are provided for work with vertebrate animals infected with agents, which may infect humans. These Animal Biosafety Levels, ABSL 1 thru 4, outlines practices, equipment, and facilities that are comparable to the laboratory biosafety levels described previously.

BIOSAFETY LEVEL	FACILITY REQUIREMENTS	PRACTICES
A-BSL1 Agent(s) used: Noninfectious	• Restricted access with external facility doors self-closing and self-locking • Designed, constructed, and maintained to facilitate cleaning and housekeeping. • Furniture can support anticipated loads and uses • Sink available for handwashing • Emergency eyewash and shower readily available • Ventilation is provided in accordance with the *Guide for the Care and Use of Laboratory Animals*.Special containment equipment is determined by risk assessment. If used, equipment is installed and operated in a manner to ensure effective operation	• Standard Microbiological Practices • All laboratory-related incidents, injuries, illnesses, and near misses are reported to EHS • Special Practices ○ None • PPE must be worn in accordance with animal facility and EHS policies
A-BSL2 Agent(s) used: Infectious spread via blood or oral/fecal transmission Includes human blood, human cell lines, toxins, venom,	All A-BSL1 requirements plus the following: • Vacuum lines protected • Autoclave available or approved alternative decontamination method • Laboratories should be under negative or neutral pressure • BSCs and other primary containment barrier systems are installed and operated in a manner to ensure their effectiveness	All A-BSL1 requirements plus the following: • Aerosol generating procedures **must** be conducted in a biosafety cabinet • Laboratory personnel demonstrate proficiency (training **must** be documented)

materials from Nonhuman primates		• Medical surveillance as appropriate • Immunizations offered as available
A-BSL3 Agent(s) used: Infectious spread via aerosol transmission	All A-BSL1 and A-BSL2 requirements plus the following: • Double door entry • Negative air flow • Biosafety cabinet(s) • Hands free sink • Laboratory **must** be sealable	All A-BSL1 and A-BSL2 requirements plus the following: • Enhanced secured access • All work conducted in biosafety cabinet
A-BSL4	No work at ABSL4 is conducted at the University of Michigan	

SECTION 5: LABORATORY ACCESS

Admittance

- The PI or his/her designee enforces institutional policies that control safety in and access to the laboratory. Persons requesting to use the laboratory or equipment shall be advised of the potential hazards involved and shall follow all U-M biosafety requirements.
- Access to the laboratory is restricted when work with biohazardous materials is in progress, after hours, or when laboratory personnel are not available.

Security

Biohazardous organisms and toxins may be of interest to persons or groups involved in terrorism or other illegal activities. These materials could pose a serious threat to humans, agriculture, or the livestock industry and **must** be kept secured.

Vaccinations (if applicable)

Laboratory personnel **must** be provided with information regarding vaccines that may be available to protect them against laboratory-acquired infection. The PI or supervisory personnel may require immunization as a condition of employment. Vaccination information that should be provided to laboratory personnel includes: efficacy, side effects, booster schedule, etc. Vaccinations should be provided to laboratory personnel free of charge and during working hours. Vaccinations are provided through U-M Occupational Health Services (OHS). Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all laboratory personnel should be provided with information regarding immune competence and conditions that may predispose them to infection.

Restrictions or Recommendations

Restrictions or recommendations will be made on an individual basis for entry or working within the lab. Examples of medical conditions that might warrant special precautions are HIV infection, immunosuppressive conditions, and drug therapies that suppress the immune system. Additionally, it is

recognized that exposure to certain infectious agents may adversely affect a fetus during pregnancy if the mother is infected with the agent, or personnel of childbearing age. Laboratory personnel, who fall into any of the above conditions, should inform their personal physician and the PI about the situation.

Biosafety Training

It is the direct responsibility of the PI or supervisory personnel to initially instruct new laboratory personnel of the safety procedures used in the laboratory. The PI is responsible for ensuring all laboratory personnel exhibit competency in good microbiological techniques prior to initiating experiments. This includes a thorough review of the appropriate operating procedures of the laboratory.

- For information regarding available training courses please go to the EHS Course Catalog
- BSL2 Laboratory personnel are required to complete Biosafety Training. Training is available through My Linc. Additional EHS training may be required based on research focus.
- U-M laboratory personnel who may reasonably anticipate contact with human blood, blood products, tissues, fluids or OPIM, including human cell lines during the performance of their duties **must** complete annual Bloodborne Pathogens training. Training is available online through My Linc.
- Lab personnel must receive lab specific training by the lab director, lab manager or other designee. This training must be documented in detail and should include topics such as; agent specific training, use of equipment, lab experimental procedures, use of rDNA and viral vectors, etc. The BSL2 Lab Member Training Packet or equivalent documentation must be maintained.
- Lab specific training documentation and SOPs should be reviewed annually.
- Laboratory personnel **must** have prior experience with the agent in use or **must** be provided with suitable and sufficient information, instruction, and training about working with the agent prior to initiating work.
- A training course entitled Working Safely with Viral Vectors is available for new or entry-level laboratory personnel who plan to use viral vectors in vitro or in vivo. The course is provided by the U-M Vector Core Laboratory and is recommended by the IBC and EHS. Registration for the course is available through My Linc.
- New laboratory personnel **must** review the U-M Biosafety Manual and associated documents listed in the BSL2 Lab Member Training Packet prior to starting work in the laboratory.

SECTION 6: CONTROLS TO REDUCE EXPOSURES

U-M Standards for Biological Laboratories

U-M Biological Safety Designated Standards

Negative Pressure

In general, a separate room provides a higher level of containment for working with biohazardous materials. Mechanical ventilation should provide an inward flow of air (negative pressure) without recirculation to spaces beyond the laboratory. U-M EHS will verify air pressurization during inspections.

Bench Tops

- Bench tops should be impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

- The work areas should be kept clean and dust free as to prevent contamination of samples and laboratory-acquired infections.

Laboratory Furniture

Laboratory furniture should be capable of withstanding anticipated loading and uses. Spaces between benches, cabinets, and equipment should be accessible for cleaning. Chairs and other furniture used in laboratory work must be covered with a non-fabric material that can be easily decontaminated. Carpets and rugs in laboratories are not appropriate.

Workplace Practice Controls

All personnel **must** routinely use appropriate controls when handling biohazards.These include:

- Engineering Controls/Primary Barriers are physical containment measures placed directly at the level of the hazard (e.g., biological safety cabinets, enclosed containers, centrifuge safety cups). Selection of the type of primary barrier should be based on the risk assessment.
- Secondary Barriers are the design and construction features of the laboratory facility (e.g., ventilation system, access control, self-closing doors). Combined with other safety controls help to provide personnel, product, and environmental protection.
- Sink is required for immediate handwashing.
- Emergency eyewash is readily available in the laboratory.

Personal Protective Equipment

Personal Protective Equipment (PPE) should be selected in accordance with the hazards identified. The *minimum level of PPE* when working in biological laboratories should include **lab coats, safety glasses and appropriate gloves**. Alternatives to latex gloves should be available. Lab coats should not be taken home for laundering. Professional laundering service is available. (See PPE Hazard Assessment in Chemical Hygiene Plan (CHP) appendix 1)

Additional PPE

PPE	DESCRIPTION
Hair Bonnet	May be required in certain animal laboratory spaces refer to PPE indicated on door sign.
Face Mask	May be required in non-human primate facilities for specific tasks.
N95 Respirator	May be required for certain allergies. Risk assessment required for use of this respiratory protection and entry into the EHS Respiratory Protection Program.
Face shield	May be required if there is a splash hazard that cannot be mitigated through other engineering controls. (See CHP appendix 1 **NOTE** 3 for proper use).
Double gloves	Two pairs of gloves may be required to mitigate risks for hazards such as needle sticks; to reduce the likelihood of cross contamination from handling biohazardous organisms; and for spill clean-up as determined by risk assessment.

PPE	DESCRIPTION
Disposable sleeve protectors	May be required as a supplement to lab coat or gown to mitigate risk for procedures with high splash potential (for example necropsy).
Foot covers	May be required in certain animal laboratory spaces, refer to PPE indicated on door sign, to reduce the likelihood of cross contamination and for spill clean-up as determined by risk assessment.
Scrubs	May be required in certain laboratory spaces, refer to PPE indicated on door sign or lab SOP, to reduce the likelihood of cross contamination and for spill clean-up as determined by risk assessment. May also be used as alternative protective clothing.
Tyvek suites	May be required in certain animal laboratory spaces, refer to PPE indicated on door sign, to reduce the likelihood of cross contamination and for spill clean-up as determined by risk assessment.
Closed front Gowns	May be required in certain laboratory spaces, refer to PPE indicated on door sign or lab SOP, to reduce the likelihood of cross contamination.
Disposable lab coats / Gowns	May be required in certain animal laboratory spaces, refer to PPE indicated on door sign. May also be used as an alternative to cloth lab coats and gowns or when laundry service is unavailable.

EHS can assist in the correct selection of PPE. Laboratory dress code includes wearing long pants or equivalent leg covering and appropriate closed toe shoes.

Proper Use and Care of PPE

- Change gloves when the gloves are contaminated, the integrity has been compromised, or when otherwise necessary.
- Do not wash or reuse disposable gloves.
- Remove PPE and wash hands when work has been completed with infectious materials and before leaving the lab. Dispose of PPE with other contaminated laboratory waste appropriately.
- Reusable PPE **must** be decontaminated prior to reuse.
- Do not wear PPE outside of the laboratory (e.g., elevators, common non-laboratory areas, stairwells)

Electronic Devices

- Using personal electronic devices (ear buds, headphones, cell phones) are discouraged when working with biological materials.
    - These devices can become contaminated if used while handling biologicals which may result in personal contamination and transfer of infectious materials outside of the laboratory.

- Wearing electronic devices may impede awareness of lab activities and emergency situations.

Posting - Labeling and Storage

The necessity for establishing policies and procedures for proper identification of hazardous biological agents within U-M laboratories is to alert support and emergency personnel who may enter the area to take precautionary measures and to restrict traffic to potentially hazardous areas.

Signs

All areas and laboratories that contain biohazardous agents **must** be posted with a lab door sign. Signage indicating the biosafety level must be clearly posted on all doors of the research or animal procedure and housing rooms. Specific agent information is not posted on the sign. Safety information for the specific agents used in the room are located in the EHS document binder in the labs or the Housing Containment Binder located in the animal containment room.

Contact EHS to obtain a lab-specific door sign using the appropriate form:

- Laboratory Door Sign Request Form

A biohazard label, incorporating the universal biohazard symbol, should be placed on the face of these signs. These signs shall:

- Indicate the biosafety level of the laboratory.
- List the name and telephone number for the PI or responsible person to facilitate contact in case of emergency.
- List the required procedures for entering and exiting the laboratory.
- PPE requirements
- Occupational health requirements (if applicable)

Labels and Tags

The universal "Biohazard" warning labels **must** be used to identify the following items:

- Containers of infectious materials; including waste and storage
- Equipment (incubators/freezers) where biohazards are stored
- Equipment which may be contaminated through normal use of biohazards
- Laboratory animals (cages) which are potentially infectious. In addition, the cage will also be labeled with the specific agent administered to the animals.

Storage of Biohazardous Materials

All infectious materials to be stored **must** be clearly labeled with the universal biohazard symbol. Additional information including contact name and emergency numbers **must** be visible on the refrigerator or freezer in case of emergency, i.e., freezer breakdown.

Materials for long-term storage **must** be annually inspected and each container **must** be checked for cracks and other damages and properly disposed or replaced. Expired and other unwanted material **must** be decontaminated properly.

In the event of a freezer melt-down, all materials that are unable to be salvaged **must** be properly treated by autoclaving or chemical disinfection prior to final disposal.

Integrated Pest Management

Pests can mechanically transfer infectious agents between laboratory samples, and potentially even carry the agents out of the laboratory itself. Thus, control and elimination of pests is a high priority to laboratory facility operations.

Pest traps, such as "sticky boards" may be used to evaluate pest presence. Traps can be requested through UM Facilities Service Center (647-2059) and should be visually inspected monthly by designated lab personnel. Evidence of the presence of pests will be reported to the PI so that appropriate pest eradication efforts can be initiated. Refer to the EHS Integrated Pest Management Guideline for further information.

Standard Operating Procedures (SOP)

Written procedures should be available for work with infectious materials. These procedures should be reviewed annually and updated whenever a procedure changes. The SOP Template can be modified for specific tasks or procedures.

These SOPs can be modified or used as part of your lab-specific training documentation:

- Adenovirus/Adenoviral Vectors: Standard Operating Procedure
- Retrovirus/Retroviral Vectors: : Standard Operating Procedure
- Biological Toxins Standard Operation Procedure –
- Needle Recapping & Handling
- Working Safely in a Biological Safety Cabinet
- Biohazard Spill Response

Multimedia Resources

We offer faculty, staff and students these resources to supplement our Environment, Health & Safety (EHS) training courses, and reinforce our U-M culture of safety and environmental protection.

- Biological Exposure Response Poster
- Laboratory Refuse Collection Poster
- Universal Human Blood and Body Fluids Precautions Poster
- Animal Allergy Poster

Inspections

Annual Biosafety inspections are conducted for work performed at BSL-2 or higher containment. The inspections ensure the lab's facilities, training, and work practices are appropriate for the approved biosafety level.

This inspection will cover the biological aspects of the research and the lab's IBC registration**.** A person (PI, Lab manager or designee) who can discuss details of the biological work must be present on the inspection.

Inspections can be scheduled by contacting BioSafetyInspections@umich.edu

Inspection Management

Accurate records and documentation are a critical part of any Biosafety Program. In order to prove that specific requirements of the Biosafety Program have been accomplished, appropriate documentation **must** be maintained. Documentation is required for the following items:

RECORDS OF…	USE THE FOLLOWING DOCUMENTS…
Biosafety training	Lab specific training documentation: to provide a record that laboratory personnel have been trained in the proper use of the specific biohazards with which they work. EHS training documentation for all lab personnel.
My Linc Training	Documentation of applicable training courses are maintained and available during inspections.
Incident/Near miss report	Work Connections Work-Related Injury/Illness Form EHS Incident and Near Miss Report Form
Inspection Reports	Biosafety inspection reports are maintained and accessed in the MISP (MI Safety Portal). Corrective actions to deficiencies noted on inspection reports must be submitted through the MISP. Biological Safety Level 2 Inspection

SECTION 7: EQUIPMENT

Pipettes

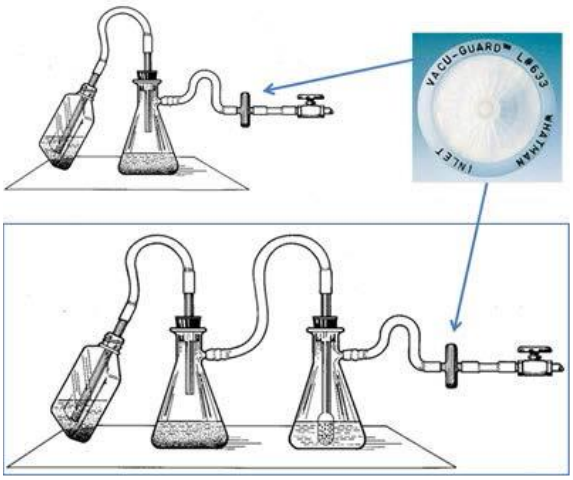
Filtered pipettes or tips should be used when pipetting biohazards, and whenever possible, glass pipettes should be replaced with disposable options.

When pipetting liquid cultures exposure to aerosols may occur when liquid from a pipette is dropped onto the work surface, or when the last drop of an inoculum is blown out. The safe pipetting techniques, which follow, are required to minimize the potential for exposure to hazardous materials.

- Mouth pipetting is prohibited.
- Contaminated pipettes should be collected for proper disposal.
- When resuspending liquid cultures, use a swirling action to create a homogeneous suspension with a minimum of aerosolization.

In-Line HEPA Filter - Protection of Vacuum Line

Vacuum lines should be protected by a high efficiency particulate air (HEPA) vacuum filter (ex. VacuShield product). Use a liquid vacuum flask(s) to collect waste. These filters can isolate and confine infectious materials, preventing fluid and aerosol contamination of vacuum pumps or aspiration suction systems. Filters are available through laboratory supply catalogs. A second vacuum collection flask may be used as a backup (see below). If this set up is placed outside of the biosafety cabinet, it should be contained in a tray or pan to prevent accidental spills.



Sharps

The use of sharps such as needles and syringes, scalpels, and other contaminated objects that can penetrate the skin should be restricted to procedures for which there is no alternative. Needles and syringes should never be used as a substitute for pipettes. When sharps **must** be used, the following procedures are recommended:

- Use safer needle devices such as: retractable device, needle locking mechanisms, etc.
- Bending, recapping, removal of needles from syringes, or otherwise manipulating needles by hand is prohibited. If it is essential that a needle be recapped the use of a mechanical device or the one handed scoop method **must** be used. This will require a lab-specific Needle Recapping & Handling SOP. Lab **must** customize this SOP to reflect the reasons for recapping needles and how this procedure will be performed.
- Sharps container **must** be located close to the use area.
- Use a hard walled container of disinfectant for reusable needles such as Hamilton syringes. Do not place reusable needles in pans containing pipettes or other glassware in order to eliminate sorting later.
- Use approved puncture resistant sharps container for disposal.
- Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, forceps or by other mechanical means.
- Plastic ware should be substituted for glassware whenever possible.

Biological Safety Cabinet

The biological safety cabinet (BSC) is the primary engineering control used to provide product, personnel, and environmental protection from and containment of infectious aerosols generated by many microbiological procedures. For work at BSL-2 aerosol generating procedures must be performed in a biosafety cabinet or other containment device.

The biological safety cabinet **must** be disinfected with the appropriate disinfectant before and after each use. Reference link below for more information on biosafety cabinet use and placement:
Working Safely in a Biological Safety Cabinet

Placement of Biological Safety Cabinets

Differences Between Laboratory Hoods

WARNING: Never operate a BSC while a warning light or alarm is on. Call EHS at (734) 647-1143 to service failing BSCs. Make sure that all biohazard materials are properly secured and notify the PI or Laboratory Manager.

Centrifuges

Centrifugation of biohazardous material shall be done using centrifuge buckets with safety features such as biocontainment lids aka safety cups/rotors with lids. If safety cups are not available an approved alternative method must be used such as a wait time. An SOP should be written for the alternative method to be used. Each person operating a centrifuge should be trained on the proper operating procedures. Improperly used or maintained centrifuges can lead to equipment failure that present significant hazards to users. The high-speed spins generated by centrifuges can create large amounts of aerosol if a spill, leak, or tube breakage occurs. In the case of equipment failure, pieces of equipment can become projectiles causing injury to laboratory personnel and damage to the lab.

The following procedures for centrifugation are recommended:

1. Fill and decant all centrifuge tubes and bottles within the BSC. Avoid filling tubes to the rim. The maximum for centrifuge tubes is ¾ full.
2. Use screw top caps on centrifuge tubes.
3. Wipe outside of tubes with disinfectant before placing in safety cups or rotors.
4. Load and unload samples inside of a biological safety cabinet.

Blenders, Ultrasonic Disrupters, Grinders and Lyophilizers

The use of any of these devices results in considerable aerosol production. Blending, cell-disrupting, and grinding equipment **must** be used in a BSC when working with biohazardous materials. If the equipment does not fit inside of the BSC, contact EHSBiosafety@umich.edu to complete a risk assessment and create a hazard-mitigation plan.

Microscopes

Tighten caps on flasks of infectious culture before transporting to the microscope. Infectious cultures in plates or other containers without tight fitting lids **must** be carried to the microscope in a sealed container. Disinfect the viewing platform of the microscope after each use.

Microtomes

Microtome blades are extremely sharp and **must** be handled with great care and stored safely when not in use. When changing the knife, stainless steel mesh gloves should be worn.

If the knife projects beyond the sectioning area, a suitable guard **must** be fitted. Always carry the knife, in its case, to the microtome. Never leave the knife on a microtome.

After use, always return the knife to its case or dispose of immediately. Slide the ''back'' on to the knife before removing it. Disinfect the microtome by wiping with bleach or sodium hydroxide solution.

Microtome & Cryostat Safety Guide

Cryostats

- Frozen sections of unfixed human tissue or animal tissue infected with a biohazardous material pose a risk of infection. Freezing tissue does not inactivate all biohazardous materials.
- Freezing propellants under pressure should not be used for frozen sections as they may cause spattering of droplets of infectious material.
- Gloves should be worn during preparation of frozen sections.
- Consider the contents of the cryostat, including trimmings and sections of tissue, to be contaminated and decontaminate it frequently with 70% ethanol.
- Remove trimmings and sections with forceps during decontamination.
- Defrost and decontaminate the cryostat with a tuberculocidal disinfectant as needed.
- Handle knives with extreme care. Stainless steel mesh gloves should be worn when changing knife blades.

Bunsen Burners (on bench top)

Bunsen burners used on the bench for sterilization of inoculating loops or needles **must** be handled with care to ensure safe use.

- If using alcohol, stabilize the alcohol container so that it cannot tip over.
- Reduce the amount of flammable chemicals, equipment, and supplies in the work area. Use only enough alcohol for the experiment or technique.
- Have a “snuffing” lid available in case the alcohol in the container catches fire. Water is not a good choice for putting out fires.
- If you smell gas, turn off the exterior gas valve and wait until the gas has fully dissipated before lighting any flames.

In place of Bunsen burners, consider using a shielded electric incinerator or hot bead sterilizer. Disposable plastic loops and needles are also good alternatives to reduce generation of aerosols.

Open Flames in Biosafety Cabinets

Open flames inside a biosafety cabinet are **NOT** permitted. Open flames create airflow turbulence that may compromise sterility and worker protection and heat buildup may damage the HEPA filters. Open flames are extremely dangerous around flammable materials, such as ethanol, which is often found in BSCs. Follow these tips for avoiding fires in your BSC:

- Use disposable pre-sterilized loops and spreaders.
- Replace Bunsen burners with alternative technology such as electric loop sterilizers, shielded electric incinerator, or hot bead sterilizer.

Bunsen Burner Alternatives

Equipment Maintenance

- Autoclaves, centrifuges, biological safety cabinets, and fume hoods should undergo regular preventative maintenance by qualified personnel.
- Biosafety cabinets must be certified annually by EHS. EHS techs will place a certification sticker onto the cabinet which includes the date the current certification expires.
- Contact EHS (734) 647-1143 to perform certification or maintenance.

- If cabinets are not functioning correctly or past certification DO NOT use and contact EHS.
- Preventative maintenance records should be kept on all equipment.

Other Hazards

Dry Ice

Dry ice is the solid form of carbon dioxide, non-combustible, and isavailable in flakes, pellets or block form. It will sublime (vaporizes directly to the gas state) at a temperature of –78.5C (-109.3 F) or higher. Dry ice is commonly purchased from a commercial manufacturer. Dry ice is commonly used to cool reactions or to ship biological specimens.

All U-M laboratory personnel **must** follow the safe storage, usage, and handling of dry ice. U-M laboratory personnel responsible for shipping packages containing dry ice **must** be properly trained according to Department of Transportation (DOT) and International Air Transport Association (IATA) Regulations. Transporting Biologicals

Storage

- Dry ice is to be stored in a well-ventilated location and placed in a Styrofoam chest, insulated cooler, or a special cooler designed for the storage of dry ice.
- Because of the thermal expansion of dry ice (one pound of dry ice produces about 250 liters of gaseous carbon dioxide), sufficient gaseous carbon dioxide can be released in a sealed container to cause an explosion. Dry ice is NEVER to be stored in any type of tightly sealed devices such as an ultra-low freezer or plastic/glass container.
- Dry ice will sublimate about five to ten pounds every 24 hours (blocks last longer) in a typical storage cooler. Plan on purchasing dry ice as close as possible to the time needed.
- Normal air is composed of 78% nitrogen, 21% oxygen, and only 0.04% carbon dioxide. Concentrations greater than 0.5% (5000 ppm) can become dangerous. Therefore, handle dry ice in well-ventilated locations.

Hazards/Precautions:

- Burns/frostbite: Dry ice can cause burns to the skin in a short period. Thermal gloves are to be used if it is necessary to handle dry ice.
- Suffocation: Carbon dioxide is a simple asphyxiant. Always store dry ice in a well-ventilated area to minimize the buildup of carbon dioxide. Personnel **must** use caution should dry ice be stored in a deep cooler. Personnel **must** never stick one's head into the chest to obtain the dry ice.
- Explosions: Placing dry ice into a tightly sealed container can permit sufficient gas build up to cause an explosion. Never place dry ice inside an ultra-low freezer or other enclosed space.
- Placement of dry ice in rooms with little or no ventilation can result in a build-up of the carbon dioxide in the area. Do not store dry ice in a confined area such as walk-in coolers, refrigerators, freezers, closets, or cars/vans.
- When using dry ice to ship materials, the shipper **must** abide to all applicable shipping regulations.

Disposal

- Dispose unneeded dry ice by letting the unused portion sublimate (recommended for well-ventilated locations because it will occur over a period of several days and the ventilation will take care of the gas liberated).
- NEVER dispose of dry ice in a sink, toilet or other drain (such action can destroy the structure because of the temperature difference).

- NEVER dispose of dry ice in the trash or garbage.
- NEVER place unneeded dry ice in corridors (some corridors may not be well ventilated and the oxygen level can be reduced to low levels).

Ultraviolet Light

The Center for Disease Control (CDC) and the National Institutes of Health (NIH) agree that UV lamps are not recommended nor required in a BSC. Proper use and cleaning of BSC negates any need for the use of UV lamps, which require regular cleaning, maintenance, and monitoring for germicidal activity.

If the laboratory decides to use UV lamps, the following protective measures **must** be adhered to:

- UV lamps **must** be turned off when the room is occupied to protect eyes and skin from UV exposure, which can burn the cornea and cause skin cancer.
- Laboratory personnel **must** wear a protective face shield and cover exposed skin.

If using fluorescent microscopes, determine whether laboratory personnel using the microscope and anyone else in the room **must** wear protective goggles or glasses.

Cleaning and Decontamination

- All areas of the laboratory **must** be kept clean and orderly.
- Dirt, dust, and clutter are safety hazards and are not consistent with acceptable biological research.
- Vacuum lines should be protected by a liquid disinfectant trap.
- Contaminated materials to be reused **must** be chemically disinfected or placed, untreated, in autoclave bin prior to autoclaving.
- Surfaces are to be decontaminated after each use.
- Appropriate disinfectants should be available specific to the agents in use. Ensure appropriate contact time for the disinfectant and biohazardous materials, follow manufacturer's recommendations.

  NOTE: Recommended disinfectants include 10% bleach 70% ethanol, Lysol, Virex, and quaternary ammonia compounds.

SECTION 8: BIOHAZARDOUS WASTE

In the laboratory, biological waste must be kept in a closed container unless actively adding to the waste. Prior to removing biological waste from the lab or collection by EHS-Hazardous Materials Management (EHS-HMM), decontaminate external surfaces/containers by spraying or wiping with appropriate disinfectant and transported in a closed secondary container.

Biological waste should be routinely removed from the lab to vendor collection areas (if available in your building), autoclaved according to building practices, chemically treated collected by EHS-HMM.

Biohazardous waste is divided into the following categories:

CATEGORY OF BIOHAZARDOUS WASTE	INCLUDES…
Solid Biohazardous Waste	Plastic plates, petri dishes, paper towels, gloves, pipette tips, plastic serological pipettes, etc. that have been used with or come in contact with biological material.
Liquid Biohazardous Waste	Culture broths, media, stock cultures, centrifuge supernatants, blood, and solutions containing recombinant and synthetic nucleic acid molecules or any liquids that contain or have come in contact with viable biological material.
Sharps Waste	Needles with or without attached syringes, razor blades, glass slides, glass vials, and anything that can puncture the skin that has been used with or come into contact with biological material.

Preparing Biohazardous Waste for Collection

- Biological waste at U-M is handled in various ways. The U-M custodial staff collect waste that has been decontaminated by the lab. U-M EHS or an approved vendor collects and processes the biological waste generated at U-M. Lab directors (faculty/lab managers/supervisors) **must** follow the EHS protocols for proper disposal of biological waste to ensure regulatory compliance, maintain a safe work place, and protect the environment. Biological Waste Disposal Information
- Laboratory Refuse Collection Poster

Autoclave

- Steam Sterilization is defined as 121C for at least 15 minutes peak temperature. The standard autoclave "cycle" is at least 45 minutes.
- Personnel operating autoclave(s) **must** be properly trained in its use. This training is provided by an experienced lab personnel or autoclave vendor.
- Autoclave Safety Training is required and available through My Linc.
- Biohazardous materials **must** not be placed in autoclaves overnight in anticipation of autoclaving the next day.
- Wrap packages to allow for steam penetration; aluminum foil may not allow steam penetration, and is **not** recommended for wrapping.
- Load the autoclave as per the manufacturer's recommendation. **Do not** overload the autoclave.
- Ensure adequate spacing of items to allow steam penetration. Insufficient spacing can prevent steam from circulating properly resulting in ineffective sterilization.
- Avoid over packing of autoclave bags.
- Do not seal bags or close bottles and other containers tightly.
- Do not stack containers.
- Always place autoclave bags/containers in a secondary container when autoclaving.
- Label waste by writing lab name and date on autoclave tape.

The changes that are seen on autoclave indicator tapes following an autoclave cycle do not guarantee that the contents of containers are sterile: they indicate only that the tape on the outside of the packages has been exposed to a certain amount of heat or steam. Proper autoclave performance is

essential for sterilization. The time required for effective sterilization depends on the size of the load, volumes of liquid and density of materials to be autoclaved. Assessing autoclave performance regularly (at least once per month) is critical, the use of a heat-resistant biological indicator (BI) such as Bacillus stearothermophilus, should be used to ensure that the cycle in use really achieves sterilization conditions.

Reference Autoclave SOP for additional information

SECTION 9: RESEARCH ANIMALS

Oversight and Regulatory Compliance

Laboratory animal facilities, operational practices, and quality of animal care **must** meet applicable standards and regulations (e.g., Guide for the Care and Use of Laboratory Animals and Laboratory Animal Welfare Regulations). For information regarding working in field environments, please refer to the EHS Field Research page.

There is potential for zoonotic disease transmission to individuals handling research animals, including non-human primates, wild caught animals and any tissues or biological samples derived from these particular animals. Refer to the EHS Species Specific Risks page for further information.

All research experiments involving animals **must** be conducted in accordance with the associated Institutional Animal Care and Use Committee (IACUC) approved protocol. Animal research that involves a hazard (biological, radiological, or chemical) **must** be reflected in the approved IACUC protocol. All work involving human derived substances, recombinant DNA and synthetic nucleic acid molecules, infectious agents, biological toxins, certain animal-derived substances, and transgenic animals **must** be registered and approved by the IBC prior to commencement of the experiment.

The IBC will make the final determination of laboratory and housing containment upon IBC review of the proposed work. The IBC has the authority to increase or lower containment levels based on risk assessment.

Animals Administered Biological Materials

Animal containment facilities are designed to protect personnel from exposure to potentially infectious materials. The containment facilities follow ABSL2 containment requirements including, maintaining rooms under negative pressure relative to all entrances and exhausting room air to the outside.

All lab staff administering biological materials to animals or staff who will be handling animals following administration **must** complete the Unit for Laboratory Animal Management Training (ULAM).

Animals assigned ABSL2 must be directly manipulated or administered biological substances within a BSC in accordance with EHS and the Animal Care & Use Program. Situations that may require deviation from this practice must be reviewed and approved prior to work beginning (e.g. stereotactic injection, large animals, large equipment).
When animals are administered biological materials, the animal handler **must** wear appropriate PPE as indicated in the IBC and IACUC protocol approvals. All disposable PPE is single use and **must** be disposed of in the designated waste container upon exiting the space. Protective eyewear including safety glasses

or goggles **must** be decontaminated and remain in the room. Restraint devices and practices should be used to reduce the risk of exposure during animal manipulation.

Equipment and surfaces **must** be decontaminated after use and floors **must** be regularly cleaned. All equipment and wastes **must** be decontaminated by autoclaving or by other appropriate means before leaving the facility or **must** be appropriately contained until this can occur.

The standard operating procedure for animals administered biological materials requiring ABSL2 housing are found on the Animals Administered a Hazardous Substance Requiring Containment web page.

Necropsy, Dissection, and Tissue Harvest

Procedures such as necropsy, dissection, and harvesting tissue from animals are considered aerosol and/or splash generating. Use of certain tools (i.e. power tools, bone saws) can increase aerosol generation and exposure risk. Large animal necropsy may have a higher risk of splashes from infectious fluids. Since sharps are used for necropsy this increases the risk of sharps related injuries.

All necropsies, dissections, or tissue harvests performed on animals administered any material designated as BSL2 or housed at ABSL2 should occur within primary engineering controls; such as a biosafety cabinet, back draft table, or other appropriate containment device. If containment housing duration determined by the IBC has been met or exceeded, then primary containment may not be required for necropsy.

Any deviations from this must be reviewed and approved by IBC and EHS staff prior to work beginning.

Common Accepted Deviations:

- ABSL2 housing duration has been met (e.g. animals administered viral vectors removed from ABSL2 after 72 hours)
- Animals infected with animal pathogens and housed at ABSL2 only due to risk to other animals
- Necropsy of large animals unable to fit inside containment devices (e.g., pigs, sheep)
- ABSL2 housing has been downgraded to ABSL1 documented by internal or external testing (e.g human cell lines tested by manufacturer to be free from pathogens of concern).
    - Documentation must be provided.
    - Human-derived substances obtained directly from patients cannot be tested nor downgraded.

SECTION 10: MEDICAL SURVEILLANCE

An appropriate medical surveillance program **must** be in place for all work that requires BSL2 containment or higher, as determined by risk assessment. Laboratory personnel **must** be provided medical surveillance and offered appropriate immunizations for agents handled or potentially present in the laboratory. Personnel using respirators **must** be enrolled in the EHS Respiratory Protection Program. Certain identifiable sub-populations may have more risk for infection with certain hazards. Listed below are some additional factors that may affect a person's risk for infection.

- Certain medical conditions; diabetes, HIV, sickle cell disease, immune disorders, blood disorders
- Illnesses
- Taking certain medications which may weaken the immune system
    - Steroids
    - Antibiotics

- Pregnancy
- Undergoing chemotherapy or radiation therapy
- Organ transplant

The PI or supervisory personnel should ensure that medical staff are informed of potential occupational hazards associated with all research. Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all personnel and particularly people of childbearing age should be provided information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify to U-M OHS provider or personal physician, their lab director, or U-M Environment Health & Safety (EHS) for appropriate guidance and counseling. Protective vaccines, if available and appropriate based on work, will be provided by Occupational Health Services (OHS) at no cost to the employee. See section 11 below for post exposure evaluation information. Refer to the Medical Surveillance or Animal Handler Medical Surveillance Program web page for more information.

SECTION 11: EMERGENCY MANAGEMENT

Spill Response Procedures for Biohazardous Material

Spills and accidents should be immediately reported to the PI and EHS (734) 647-1143. EHS may be contacted for assistance with biohazardous material spills. Complete EHS Incident/Near Miss form.

Spill in the Laboratory

1. Alert others in the lab, post a warning sign if necessary and inform your supervisor. Review clean-up procedures, assemble decontamination materials and PPE.
2. Don PPE; lab coat, gloves, and safety glasses.
3. Remove sharp objects using a mechanical means and place into a sharps container.
4. Carefully cover spilled material with a paper towel. After the paper towel is in place, wet with an appropriate disinfectant.
5. Allow appropriate contact time according to manufacturer instructions.
6. Transfer all contaminated materials (paper towels, gloves, labware, etc.) into biohazard waste containers for disposal.
7. Place all remaining contaminated materials, including protective clothing, into an autoclave bag or biohazard waste container.
8. Wash hands with soap and water.
9. Complete the EHS Incident/Near Miss Report form.

WARNING

DO NOT ENTER

SPILL CLEAN-UP IN PROGRESS

Contact _____

Phone Number _____

Spill in the Biosafety Cabinet

NOTE: Leave the cabinet turned on.

1. Don double gloves, a lab coat, and eye protection.
2. Carefully cover spilled material with a paper towel. After the paper towel is in place, wet with an appropriate disinfectant. Let stand 15-20 minutes, wipe up and wash surface with appropriate disinfectant.
3. Spray or wipe cabinet walls, other work surfaces, and equipment with the appropriate disinfectant
4. If necessary, flood the work surface, drain pan, and catch basin below the work surface with disinfectant. Allow at least 15-20 minutes of contact time.
5. Soak up the disinfectant and drain the catch basin into a container. Lift the front exhaust grille and tray and wipe all surfaces. Ensure that no foreign materials are blown into the area below the grille.
6. If a 10% bleach solution is used on metal surfaces, rinse with water or 70% ethanol after decontamination is complete.
7. If the spill overflows into the interior of the cabinet, more extensive decontamination of the cabinet may be necessary. Contact EHS (734) 763-6973 for decontamination of the cabinet.

Personnel Exposure

1. If clothing or PPE are contaminated, remove potentially contaminated garments immediately and decontaminate garments by saturation with 70% ethanol or place in autoclave bag for autoclaving.
    a. Wash hands and other potentially exposed skin surfaces thoroughly with soap and water.
    b. **If** clothing or shoes are contaminated, carefully remove and place in an autoclave bag or another container. Contaminated items can be decontaminated by treatment with appropriate disinfectant such as 10% Bleach or Lysol. Contaminated items may also be autoclaved or collected for disposal. Do not take contaminated items home.
2. If there is an agent-specific protocol for exposures, follow that (e.g., HIV, Herpes B).
3. In case of needlestick or sharps injury:
    a. Expose wound and wash with soap and water.
    b. Do not squeeze the wound to induce bleeding.
4. In the case of skin contact or mucous membrane exposure:
    a. Skin
        i. Thoroughly wash area with soap and water.
        ii. Avoid use of abrasive chemical soaps or disinfectant washes as they can cause skin abrasions and a possible additional route of entry for the agent.
    b. For mucous membranes (nose, mouth or skin), flush for a minimum of 15 minutes with water.
    c. For eyes, irrigate with water or saline solution for 15 minutes.
5. Seek treatment at appropriate treatment facility (U-M- OHS, UHS, or UM Emergency Department) for **post exposure** evaluation following:
    a. Contact with mucous membranes
    b. Contact with non-intact skin
    c. Percutaneous exposure
    d. Any type of exposure that involves biohazardous materials
6. For any exposure with Bloodborne Pathogens (Human blood, OPIMs):
    a. For Michigan Medicine employees:

i. Use Michigan Medicine paging website and page # 5356.
ii. This requires a level 2 password.
iii. A nurse will return your page.

b. For Campus employees:
i. Call hospital operator at 734-936-4000 and ask operator to page #5356.
ii. State employee exposure.

7. Post exposure the following steps **must** be completed:
   a. Accident-Illness Report Form (http://www.workconnections.umich.edu/employees/work-related-illness-injury/step-one/) submit to Work Connections (within 24 hours).
   b. Report incident to EHS via Incident and Near Miss Form https://ehsa.oseh.umich.edu/EHSA/public/injuryillnesssubmit/injuryillnessinitialedit. If you have questions, please call (734) 647-1143.
   c. Report to Supervisor/PI

Treatment Facilities

- U-M OHS -- Campus Employees
  Mon-Fri 7:00 am – 5:00 pm
  Contact for current hours as they may vary
  C380 Med Inn building
  1500 East Medical Center Drive, Ann Arbor (734) 764-8021

- University Health Services -- University students (non-life threatening conditions)
  Mon-Fri 8 am – 4:30 pm, Sat 9 am – 12 pm
  Contact for current hours as they may vary
  207 Fletcher Street, Ann Arbor (734) 764-8320

- UMHS Emergency Department -- after clinic hours or on weekends or life-threatening emergency
  1500 East Medical Center Drive, Ann Arbor, (734) 936-6666

Exposures to Recombinant DNA:

1. Wash the area thoroughly with soap and water.
2. Cover the wound with a sterile dressing.
3. Following this, reporting **must** occur to:
   - PI or Director of Lab (immediately)
   - BSO (734) 647-1143 (immediately)
   - Report incident to EHS via Incident and Near Miss Form (Immediately) https://ehsa.oseh.umich.edu/EHSA/public/injuryillnesssubmit/injuryillnessinitialedit.
   - Complete an Accident-Illness Report Form (http://www.workconnections.umich.edu/employees/work-related-illness-injury/step-one/) submit to Work Connections (within 24 hours)
   - IBC (may be reported through the Biosafety Officer)
   - NIH/OBA (report will be coordinated by the IBC)

SECTION 12: TRANSPORTING BIOLOGICAL MATERIALS

The movement of biohazardous materials, chemicals, or research animals can fall under various federal and state regulations. U-M forbids the movement of these materials on university modes of public transportation such as the U-M buses, where individuals unfamiliar with the materials may be potentially exposed or have the perception of exposure.

For more information, refer to the Transporting Biological Materials Webpage.

SECTION 13: SELECT AGENTS

Researchers who wish to obtain or transfer Select Agent pathogens or regulated amounts of Select Agent toxins, specifically listed by CDC and USDA, **must** contact EHS Biosafety at EHSBiosafety@umich.edu for additional information and guidance.

Certain select agent materials that meet regulatory criteria are exempt from registration with the CDC/APHIS. Laboratories using quantities of toxins below federally established thresholds are required register with the IBC and complete the EHS Toxin Declaration Form.

SECTION 14: EHS BINDER DOCUMENTS

1. Roster of Approved Laboratory Personnel and Training Records
2. Agent list from (Research Agents form or PI's IBC summary)
3. BSL2 Lab Member Training Packet
4. Pathogen Safety Data Sheets for Infectious Agents Located in Laboratory (if applicable)
5. Standard Operating Procedures (Download template)
6. Autoclave Use Log (if applicable)
7. Hepatitis B Vaccination Form (PDF) (if applicable)
8. Prion and Prion-like Protein Guidance
9. Incident Report Help Guide

SECTION 15: GLOSSARY OF TERMS

TERM	DEFINITION
Biohazardous Material	Any material known to harbor organisms or agents capable of infecting or infesting human or animal hosts or causing environmental harm if released.
Biosafety	Biosafety is a specialized practice for proper handling and working with biohazardous organisms or biological material, which may harbor biohazardous organisms. Biosafety fits neatly into the traditional programmed approach to safety: • Administrative controls to standardize methods to reduce exposure risk • Mechanical engineering controls for containment of hazardous materials • Medical surveillance and PPE for potentially exposed laboratory personnel • Workplace monitoring to determine exposure levels
Biosafety Levels (BSL)	Describe the combination of safety practices, safety equipment and facility design used to contain the hazards associated with specific risk groups of microorganisms and is based on risk assessment. Biosafety levels are different from risk groups; however, risk group information is critical in determining the correct biosafety containment level.
Blood borne Pathogen	Pathogenic microorganisms that are present in human blood or Other Potentially Infectious Materials (OPIM) and can infect and cause disease in persons who are exposed to blood containing the pathogen. These pathogens include, but are not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV). Review the U-M ECP for further details on BBPs, link found in Section 1.
Containment	Primary Containment – The protection of personnel and the immediate laboratory environment from exposure to biohazardous material is provided by both good microbiological technique and use of appropriate safety equipment. Secondary Containment – The protection of the environment external to the laboratory from exposure to infectious materials, is provided by a combination of facility design and operational practices
EHS	University of Michigan, Department of Environment, Health & Safety
IACUC	Institutional Animal Care and Use Committee; The IACUC ensures that the highest animal welfare standards are maintained along with the conduct of accurate, valid scientific research through the supervision, coordination, training, guidance, and review of every project proposed to include the use of vertebrate animals at the U M
Infectious Substance	A viable micro-organism, or its toxin, which causes or may cause disease in humans or animals, and includes those agents listed in 42

TERM	DEFINITION
	CFR 72.3 or any other agent that causes or may cause severe, disabling, or fatal disease.
IBC	Institutional Biosafety Committee; The IBC is responsible for assessing the biosafety containment level for research involving recombinant DNA, synthetic nucleic (including human gene transfer studies) infectious agents, biological toxins, human-derived tissues, fluids and cells, certain animal-derived tissues, fluids and cells, federally-regulated Select Agents, experiments with Dual Use Research of Concern potential, and research requiring BSL3 containment
MI Safety Portal (MISP)	Data management system that is used to support U-M's EHS compliance for our research community. This comprehensive system will allow users to easily and efficiently manage their EHS compliance by accessing applicable training, inspection, inventory and other records and reports.
Occupational Exposure	An exposure that may place personnel at risk of injury or infection is defined as percutaneous (e.g., a needle stick or cut with a sharp object), contact of mucous membranes, or contact of skin (especially when the exposed skin is chapped, abraded, or afflicted with dermatitis or the contact is prolonged or involving an extensive area) with blood, tissues, or other bodily fluids to which universal precautions apply. For the purpose of this manual, the occupational exposure **must** be to fluids or aerosols known to be infectious.
OPIM	Materials in addition to human blood that may be capable of transmitting bloodborne pathogens. Review the U-M ECP for further details on OPIMs, link found in Section 1.
UMOR	University of Michigan Office of Research
Potentially Infectious Material	Any material, which may or is known to contain an etiologic agent of human or animal disease.
Principal Investigator/Lab Director	The University of Michigan faculty member responsible for the research underway in the laboratory. For the purposes of this protocol, the Principal Investigator is
Recombinant DNA Molecules	Molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell; or molecules that result from the replication of those described above.
Risk Groups	Are the classification of infectious microorganisms based on principle characteristics such as; route of transmission and severity of disease. See below
Standard Microbiological Practices (SMP)	Basic safe laboratory work protocols for working with biological materials based on containment level. The main objective of SMP is to provide safety controls needed to protect workers and the environment from contamination in the event that the agents are accidentally released from their primary container.

SECTION 16: REVISION HISTORY

Revisions to online UM Biosafety Manual

Date	Details of revision
6-4-19	Medical surveillance section 10, added details regarding immunocompetence pg 18
6-14-21	Section 4, update from 6th edition of BMBL, eyewash and biosafety manual added at BSL1. Section 5 Biosafety Training, Added EHS Course Catalog, removed broken links to specific course numbers. Added more detail on lab specific training. Section 6, added Standard Operating Procedures Section. Section 11 Personnel Exposure, updated reporting for BBP exposures, updated OHS hours, updated Personnel exposure section. Section 14, took out "Required." The binder documents are meant to help labs with lab specific training. Other forms/methods may be used besides the EHS forms. Section 15 Glossary of terms, updated Bloodborne pathogen definition. Added brief definition for OPIM.
6-23-21	Section 6: Added Multimedia resources section. Updated Section 6: SOPs. Updated Section 3. Updated Section 5: Admittance. Added MISP to glossary. Section 7: Biosafety Cabinets, added placement guidance document, and differences between hoods document. Section 7: Centrifuges, updated. Section 7: Open flames in BSCs, added alternatives document.
2-1-22	Updated SMPs, added BSL2 Lab Member Training Packet
3-08-23	Section 1: Updated U-M Biological Materials Policy Statement to include IBC policy for adherence to the UM Biosafety Manual Section 3: Updated SMPs for consistency with BMBL Section 4: Updated Biosafety Levels and Animal Biosafety Levels for consistency with BMBL Section 6: Added additional information for sign requirements. Updated sharps section. Section 9: New subsection "Animals Administered Biological Materials" including new information on requirements for administration, dissection, necropsy, and tissue harvest
7/6/23	Removed all instances of the Needlestick Exposure Guide and replaced it with the Biological Exposure Response Guide
11/3/23	Added Incident Report Help Guide and Prion & Prion-like Protein Guidance documents to Section 14.
5/7/24	Exposure response contact/page information updated. Added wording describing animal housing downgrade and necropsy requirements for human-derived material. Updated biological waste section in accordance with CDC guidance. Updated Section 6 adding Electronic devices section.
6/18/24	Annual review
01/30/25	Section 6: Updated the Biological Exposure Response Guide Section 7: Updated previously broken link to the Microtome and Cryostat Safety Guide
4/29/25	Section 11: Updated emergency response. Added warning sign for spills. Section 8: Updated autoclave section.
5/7/25	Section 13: Updated link to the Toxin Declaration Form