I. PURPOSE

The purpose of the Eastern Michigan University (EMU) Biosafety Program is to protect faculty, staff, lab and teaching assistants, student employees and students from exposures to biological agents and biohazardous materials in laboratories. This program has been developed to comply with the U.S. Department of Health and Human Services Public Health Service, Centers for Disease Control and Prevention and National Institutes of Health "Biosafety in Microbiological and Biomedical Laboratories" (BMBL) requirements and the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines).

II. SCOPE AND APPLICATION

All EMU departments working with biological and biohazardous materials are required to comply with the Biosafety Program. This program applies to all employees (faculty, staff, lab and teaching assistants, student employees and students) working in laboratories who may be exposed to biohazardous materials during the course of their routine work or in an emergency.

III. BIOSAFETY PROGRAM REQUIREMENTS

Each department working with biohazardous materials must ensure the requirements of the Biosafety Program are followed. These requirements include, but are not limited to:

- Provide Biosafety training to all affected employees and students prior to their working with biohazardous materials.
- Develop written standard operating procedures (SOPs) for operations involving biohazardous materials.
- Prepare an emergency response plan for biohazardous spills and exposures.
- Provide vaccinations and medical monitoring as required by this program.
- Ensure no biosafety level 3 or 4 work is conducted at EMU.
- Maintain written documentation of SOPs and training records.

The integrity of the Biosafety Program is compromised if employees, faculty and/or students violate the standards and the supervisor, faculty, department head and/or dean take no actions. Disciplinary action should be taken by faculty in teaching and research labs when students violate the rules and by supervisors and/or department heads when employees and/or faculty violate the rules. Subject to the provisions of the specific collective bargaining agreement for the employee, disciplinary action will depend on the seriousness of the violation, if it is a repeat violation and/or if injuries occurred. The Deans and Human Resources should become involved when there are repeated violations and/or a pattern of non-compliance.

IV. DEFINITIONS

Biohazardous materials – items containing or contaminated with blood, other infectious materials and/or biological agents.

Biological agents – include bacteria, viruses, fungi or other microorganisms and their associated toxins.

Biological Safety Cabinet (BSC) – the principal device used to provide containment of infectious droplets or aerosols generated by many microbiological procedures. There are three types of BSCs (Class I, II and III).

Biosafety – the knowledge, techniques and equipment used to prevent personal, laboratory and environmental exposure to potentially infectious agents or biohazards, including the containment conditions under which infectious agents can be safety handled.

Biosafety Levels (BSLs) – risk assessment-based classification of the activities involving infectious microorganisms and laboratory animals in ascending order, by degree of protection provided to personnel, the environment and the community.

Biosafety Level	Agents
1	Not known to consistently cause diseases in healthy adults.
2	Agents associated with human disease. Routes of transmission include percutaneous injury, ingestion and mucous membrane exposure.
3	Indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure.
4	Dangerous/exotic agents which pose high individual risk of aerosol-transmitted laboratory infections that are frequently fatal, for which there are no vaccines or treatments. Agents with a close or identical antigenic relationship to an agent requiring BSL-4 until data are available to re-designate the level. Related agents with unknown risk of transmission.

Bloodborne Pathogens – pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

Infectious Agents – any material that can cause an infection that can lead to a disease.

Occupational Exposure – reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of one's work duties.

Other Potentially Infectious Material – includes any of the following human body fluids: semen, vaginal secretions, amniotic fluid, cerebrospinal fluid, peritoneal fluid, pleural fluid, pericardial fluid, synovial fluid, saliva in dental procedures, any body fluid that is visibly contaminate with blood, all body fluids in situations

Primary Barrier/Containment – safety equipment (BSC, enclosed containers and other engineering controls) designed to remove or minimize exposures to hazardous biological materials.

Principal Investigator (PI) – faculty responsible for the research being conducted in a particular laboratory.

Recombinant Nucleic Acid Molecules – are DNA or RNA molecules formed by laboratory methods of genetic recombination that bring together genetic material from multiple sources, creating sequences that would not otherwise be found in the genome.

Risk Groups (RG) – Classification of biological agents known to infect humans as well as selected animal agents that may pose theoretical risks if inoculated into humans. There are four risk groups:

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

Secondary Barrier/Containment – the design and construction of laboratory facilities that contributes to the laboratory workers' protection, provides a barrier to protect persons outside the laboratory and protects persons or animals in the community from infectious agents that may be accidentally released from the laboratory.

Select Agents – biological agents and toxins that have been determined to have the potential to pose a severe threat to public health and safety, to animal and plant health or to animal or plant products. List of HHS and USDA Select Agents and Toxins.

Standard Microbiological Practices - basic laboratory and hygiene practices that apply to laboratories working with microorganisms or any biological material that contains or may contain microorganisms.

Standard Operating Procedures (SOPs) – any of the following that address the performance of work activities so as to reduce the risk of exposure to blood and other potentially infectious materials: written policies, procedures, directives, standards of practice, protocols, systems of practice and/or elements of an infection control program.

V. RESPONSIBILITIES

A. Deans, Directors and Department Heads

1. Provide leadership and the management systems necessary to ensure safe working conditions are maintained in their Colleges and Departments.
2. Ensure the Biosafety Program is implemented as applicable.
3. Motivate and assist faculty, managers and supervisors with biosafety program compliance.
4. Require faculty, staff, graduate assistants and student employees to attend all applicable trainings.
5. Ensure all affected students receive appropriate biosafety training.
6. Enforce disciplinary actions for faculty and staff violating the requirements of the biosafety program.

B. Faculty, Managers, Principal Investigators and Supervisors

1. Perform biological risk assessments for all work involving biological agents, recombinant nucleic acid molecules and/or synthetic DNA.
2. Develop SOPs for biohazardous operations.
3. Enforce the requirements of the Biosafety Program.
4. Ensure vaccinations and/or medical monitoring are provided as needed.
5. Conduct safety inspections to ensure compliance.
6. Correct safety deficiencies in a timely manner.
7. Report biosafety concerns to Environmental Health and Safety.
8. Ensure appropriate training is provided to all laboratory employees and students.
9. Document all training.

C. Employees

1. Comply with the requirements of the Biosafety Program and departmental SOPs and safety rules.
2. Attend all required biosafety trainings.
3. Use all required personal protective equipment (PPE).
4. Report possible safety hazards and any PPE defects to your supervisor.
5. Report signs and symptoms of possible exposures, known exposures, accidents and near misses to your supervisor.
6. Participate in vaccination and medical monitoring programs.

D. Environmental Health and Safety (EHS)

1. Coordinates the Biosafety Program.
2. Develops and updates the Biosafety Program.
3. Provides generic biosafety training.
4. Conducts periodic inspections of laboratories working with biohazardous materials.
5. Maintains documentation of EHS provided trainings and inspections.
6. Provides consultation and exposure monitoring as needed.
7. Oversees the biohazardous waste disposal program.
8. Liaison with outside regulatory agencies.

E. Institutional Animal Care and Use Committee (IACUC)

1. Regulatory oversight of animal research on campus.
2. Assurance of ethical treatment of animals and research protocols.
3. Approval of all animal research projects.

F. Institutional Biosafety Committee (IBC)

1. Regulatory oversight of recombinant DNA or synthetic nucleic acid molecule, and biological research, including infectious agents, biological toxins, human and animal derived tissues, fluids and cells and Select Agents on campus.
2. Ensures the requirements of the NIH Guidelines are followed.
3. Approval of all biological and recombinant or synthetic nucleic acid research projects and use of biological agents, including Select Agents, and/or nucleic acids.

G. Office of Research Compliance (ORC)

1. Provides oversight of campus research activities.
2. Assists faculty with research concerns.
3. Provides research compliance consultation.
4. Ensures research is conducted responsibly, ethically and within regulatory requirements.
5. Oversees the IACUC and IBC.

VI. PROCEDURES

A. Submission of the EMU IBC Protocol Application for Work with Biological Agents and/or Recombinant or Synthetic Nucleic Acids

1. Prior to any work with biological agents or any form of recombinant or synthetic nucleic acid molecules, the EMU IBC Protocol Application for working with these materials must be submitted to the IBC. The Principal Investigator is responsible for ensuring all research staff comply with IBC policies, procedures and the NIH Guidelines.
2. In order to complete the application, the following risk assessments for the proposed work must be completed.
   a. Biological Risks
   b. Hazardous Laboratory Procedures
   c. Work Practices, Safety Equipment and Facility Safeguards
   d. Biosafety Level Determination

B. Biological Risk Assessment

1. A risk assessment must be conducted to determine the hazardous characteristics of a known infectious or potentially infectious agent or material, the activities that can result in a person’s exposure to an agent, the likelihood that such exposure will cause a laboratory acquired infection (LAI) and the probable consequences of such an infection. The risk assessment information is then used to determine the

appropriate biosafety levels and microbiological practices, safety equipment and facility safeguards that are needed to prevent LAIs.

2. The risk assessment should be used to educate laboratory staff on the hazards of working with infectious agents and the need for developing proficiency in the use of selected safe practices and containment equipment.
3. Risk assessments must use prudent judgement. Adverse consequences are more likely to occur if risks and underestimated. However, overestimation of risk could result in unnecessary expenses and burdens for the laboratory staff. Unnecessary burdens can result in circumvention of required safeguards. If there is insufficient evidence to make a clear determination of risk, it is prudent to implement additional safeguards until additional information is available.
4. There are two broad categories for risk assessment and selection of precautions: agent hazards and laboratory procedure hazards.
5. Laboratory staff capabilities, including training, technical proficiency, and good laboratory habits and the operational integrity of containment equipment and facility safeguards must all be considered in the assessment.
6. The BMBL agent summary statement should be used to identify the primary agent and procedure hazards for specific pathogens and recommended precautions for their control.
7. The BMBL uses Risk Groups to determine the hazardous classification of biological agents.
8. For work involving genetically modified agents, risk assessments shall be completed based on the NIH guidelines.

C. Hazardous Laboratory Procedures Assessment

1. Review laboratory procedures to determine potential routes of exposure. These include:
   a. Use of syringe needles or other sharps.
   b. Spills and splashes onto skin and mucous membranes.
   c. Ingestion via mouth pipetting.
   d. Animal bites and scratches.
   e. Inhalation of infectious aerosols.
2. Procedures that generate aerosols or impart energy into a microbial suspension should be minimized if possible and containment requirements defined in the lab's SOPs.

D. Work Practices, Safety Equipment and Facility Safeguards Assessment

1. Identify any potential deficiencies in the practices of the laboratory workers.
2. Review training, experience, knowledge of the agent and procedure hazards, good habits, caution, attentiveness and concern for the health of coworkers and staff members. Provide additional training and oversight as needed to ensure exposure risks are eliminated.
3. Review personal protective equipment requirements for the laboratory. Provide additional training as needed.
4. Review safety equipment (biological safety cabinets, centrifuge safety cups, sealed rotors, etc.) for proper operation and maintenance. Provide training as needed.

5. Review facility safety features, e.g., negative pressure into tissue culture rooms and ensure proper operation. Submit work orders as necessary.

E. Biosafety Level Determination

1. Based on all of the above and use of the BMBL, determine the biosafety level and any additional laboratory precautions needed to safely conduct work with biological agents and/or nucleic acids.
2. Upon completion of the assessments and application, submit the application to the IBC.

F. Biosafety Level 1 Criteria

Biosafety Level 1 is suitable for work involving well-characterized agents not known to consistently cause disease in immunocompetent adult humans and present minimal potential hazard to laboratory personnel and the environment. BSL-1 laboratories are not necessarily separated from the general building traffic patterns. Work is typically conducted on open bench tops using standard microbiological practices. Special containment equipment or facility design is not required, but may be used as determined by appropriate risk assessments. Laboratory personnel must have specific training in the procedures conducted in the laboratory and must be supervised by a scientist with training in microbiology or related science. The following standard practices, safety equipment and facility requirements apply to BSL-1.

1. Standard Microbiological Practices
   a. The laboratory supervisor must enforce the EMU laboratory access control policies.
   b. The laboratory supervisor must ensure laboratory personnel receive the appropriate training for their duties, the necessary precautions to prevent exposures and exposure evaluation procedures.
   c. Lab personnel must receive annual updates or additional training when procedural or policy changes occur.
   d. Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all laboratory personnel, particularly women of childbearing age, should be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify to EMU's healthcare provider for appropriate counseling and guidance.
   e. Persons must wash their hands after working with potentially hazardous materials and before leaving the laboratory.
   f. Eating, drinking, handling contact lenses, applying cosmetics and storing food for human consumption is not permitted in the laboratory. Food must be stored outside the laboratory in cabinets or refrigerators designated and used for this purpose.
   g. Mouth pipetting is prohibited; mechanical pipetting devices must be used.
   h. The safe handling procedures for the use of sharps, such as needles, scalpels, pipettes and broken glassware must be followed. These include, but are not limited to:

i. Needles must not be bent, sheared, broken, recapped, removed from disposable syringes or otherwise manipulated by hand before disposal.
ii. Used disposable needles and syringes must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal. These are available from EHS.
iii. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
iv. Broken glassware must not be handled directly. It must be removed using a brush and dustpan, tongs or forceps. Plastic-ware should be substituted for glassware whenever possible.

i. Minimize the creation of splashes and/or aerosols.
j. Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectants.
k. Decontaminate all cultures, stocks and other potentially infectious materials before disposal using an effective method. Depending on where the decontamination will be performed, the following methods should be used prior to transport:
   i. Materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof container and secured for transport.
   ii. Materials to be removed from the facility for decontamination must be packed in accordance with applicable local, state and federal regulations.
l. A biohazard sign must be posted at the entrance to the laboratory when infectious agents are present. The sign must also include up to date contact information.
m. Pest management concerns must be reported to the Physical Plant immediately.

2. Special Practices
   a. None required
3. Safety Equipment (Primary Barriers and Personal Protective Equipment)
   a. Special containment devices or equipment, such as BSCs, are not generally required.
   b. Protective laboratory coat, gowns, or uniforms are recommended to prevent contamination of personal clothing.
   c. Wear protective eyewear when conducting procedures that have the potential to create splashes of microorganisms or other hazardous materials. Persons who wear contact lenses in laboratories should also wear eye protection.
   d. Gloves must be worn to protect hands from exposure to hazardous materials. Glove selection should be based on an appropriate risk assessment. Alternatives to latex gloves should be available. Wash hands prior to leaving the laboratory. In addition, BSL-1 workers should:
      i. Change gloves when contaminated, glove integrity is compromised or when otherwise necessary.
      ii. Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory.
      iii. Do not wash or reuse disposable gloves. Dispose of used gloves with other contaminated laboratory waste. Hand washing protocols must be rigorously followed.

4. Laboratory Facilities (Secondary Barriers)
    a. Laboratories should have doors for access control.
    b. Laboratories must have a sink for hand washing.
    c. The laboratory must be easily cleaned, carpet and rugs are not allowed.
    d. Laboratory furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets and equipment should be accessible for cleaning.
        i. Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis and other chemicals.
        ii. Chairs used in laboratory work must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectants.
    e. Laboratory windows that open to the exterior must have screens.

G. Biosafety Level 2 Criteria

Biosafety Level 2 builds upon BSL-1. BSL-2 is suitable for work involving agents that pose moderate hazards to personnel and the environment. It differs from BSL-1 in that: 1) laboratory personnel have specific training in handling pathogenic agents and are supervised by scientists competent in handling infectious agents and associated procedures; 2) access to the laboratory is restricted when work is being conducted; and 3) all procedures in which infectious aerosols or splashes may be created are conducted in BSCs or other physical containment equipment. The following standard and special practices, safety equipment and facility requirements apply to BSL-2.

1. Standard Microbiological Practices

    All the Standard Microbiological Practices of BSL-1 must be followed.

2. Special Practices
    a. All persons entering the laboratory must be advised of the potential hazards and meet entry/exit requirements.
    b. Laboratory personnel must be provided medical surveillance, as appropriate, and offered available immunizations for agents handled or potentially present in the laboratory.
    c. Serum samples shall be collected and stored separately from at risk personnel.
    d. The laboratory must have a laboratory specific biosafety manual that is readily available and the requirements enforced.
    e. The laboratory supervisor must ensure laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with BSL-2 agents.
    f. Potentially infectious materials must be placed in a durable, leak proof container during collection handling, processing, storage or transport within a facility.
    g. Laboratory equipment should be routinely decontaminated, as well as after spills, splashes, or other potential contamination.
        i. Spills involving infectious materials must be contained, decontaminated and cleaned up by staff properly trained and equipped to work with infectious materials.

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

h. Incidents that may result in exposure to infectious materials must be immediately evaluated and treated according to procedures described in this program. All such incidents must be reported to the laboratory supervisor. Medical evaluation, surveillance and treatment should be provided and appropriate records maintained.

i. Animals and plants not associated with the work being performed must not be permitted in the laboratory.

j. All procedures involving the manipulation of infectious materials that may generate an aerosol should be conducted within a BSC or other physical containment devices.

3. Safety Equipment (Primary Barriers and PPE)

a. Properly maintained BSCs, other appropriate personal protective equipment or other physical containment devices must be used whenever:

i. Procedures with a potential for creating infectious aerosols or splashes are conducted. These may include pipetting, centrifuging, grinding, blending, shaking, mixing, sonicating, opening containers of infectious materials, inoculating animals intranasally and harvesting infected tissues from animals or eggs.

ii. High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory using sealed rotor heads or centrifuge safety cups.

b. Protective laboratory coats, gowns, smocks, or uniforms designated for laboratory use must be worn while working with hazardous materials. Remove protective clothing before leaving for non-laboratory areas, (e.g., cafeteria, library and administrative offices). Dispose of protective clothing appropriately, or deposit it for laundering by the institution.

i. Currently, EMU does not have laundry facilities. Departments with biologically contaminated items for laundering must coordinate laundry services with a professional cleaning company able to handle biohazardous materials.

ii. Contaminated laundry delivered/picked-up or sent to a laundry service must be labeled or color-coded as biohazardous and the person turning over the laundry must indicate that it is contaminated with blood or other infectious materials.

iii. In lieu of coordinating laundry services, disposable lab coats may be used. Unless grossly contaminated, these may be disposed of in the normal trash.

iv. Laboratory clothing should not be taken home.

c. Eye and face protection (goggles, mask, face shield or other splatter guard) is used for anticipated splashes or sprays of infectious or other hazardous materials when the microorganisms must be handled outside the BSC or containment device. Eye and face protection must be disposed of with other contaminated laboratory waste or decontaminated before reuse. Persons wearing contact lenses must also wear eye protection.

d. Gloves must be worn to protect hands from exposure to hazardous materials. Glove selection is based on an appropriate risk assessment. Alternatives to latex gloves should be available. Gloves must not be worn outside the laboratory. In addition, BLS-2 laboratory workers should:

i. Change gloves when contaminated, glove integrity is compromised or when otherwise necessary.
ii. Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory.
iii. Do not wash or reuse disposable gloves. Dispose of used gloves with other contaminated laboratory waste. Hand washing protocols must be rigorously followed.

e. Eye, face and respiratory protection should be used in rooms containing infected animals as determined by the risk assessment.

4. Laboratory Facilities (Secondary Barriers)
   a. Laboratory doors should be self-closing and have locks.
   b. Laboratories must have a hand washing sink. The sink may be manually, hands-free or automatically operated. It should be located near the exit door.
   c. The laboratory should be designed so that it can be easily cleaned and decontaminated. Carpets and rugs are not permitted.
   d. Laboratory furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets and equipment should be accessible for cleaning.
      i. Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
      ii. Chairs used in laboratory work must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.
   e. Operable windows to the outdoors are not recommended but must have screens if present.
   f. BSCs must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. BSCs should be located away from doors, windows that can be opened, heavily traveled laboratory areas and other possible airflow disruptions.
   g. Vacuum lines should be protected with liquid disinfectant traps.
   h. An eyewash station must be readily available.
   i. There are not specific requirements for ventilation systems. However, planning of new facilities should consider mechanical ventilation systems that provide an inward flow of air without recirculation to spaces outside the laboratory.
   j. HEPA filtered exhaust air from a Class II BSC can be safely recirculated back into the laboratory environment if the cabinet is tested and certified at least annually and operated according to manufacturer's recommendations. BCSs can also be connected to the laboratory exhaust system by either a thimble (canopy) connection or directly exhausted to the outside through a hard connection. Provisions to assure proper safety cabinet performance and air system operation must be verified.
   k. A method for decontaminating all laboratory wastes should be available in the facility (e.g., autoclave, chemical disinfection, incineration or other validated decontamination method).

H. Biosafety Level 3 and 4 Work and work with Select Agents Are Not Permitted at EMU.

I. Working with Animals and Biological Materials

For work with vertebrate animals involving biological materials, please consult with the EMU IACUC and the University Veterinarian.

J. Working with Blood and Other Potentially Infectious Materials

Laboratory work involving human blood and other potentially infectious materials must comply with Eastern Michigan University's Exposure Control Plan.

K. Laboratory Biosecurity

While the labs at EMU are Biosafety Levels 1 and 2 and do not have select agents or toxins, measures must be in place to maintain control over and account for research materials, protect relevant sensitive information and access to the facility. This includes, but is not limited to the following:

1. Prevent unauthorized access, theft, loss, release or misuse of microorganisms, biological materials and research-related information.
2. Limit access to laboratories, research materials and information.
    a. Laboratory doors should be self-closing and have locks.
    b. Access to the laboratory must be limited when work with biological agents is in progress.
    c. Infectious agents should be stored in locked cabinets/refrigerators and the room should also lock.
    d. Laboratories should not have operable windows.
    e. Research should not be left unattended or unsecured.
    f. Data should be stored on secure computer networks.
    g. Hard copies should be locked in file cabinets.
3. Maintain an inventory for control and tracking of biological stocks and other sensitive materials.
    a. MTAs are required for sending and receiving physical materials or samples used for research.
    b. Shipping of biological agents must comply with International Air Transport/ International Civil Aviation and Department of Transportation regulations.
    c. In order to ship biological agents, you must have a Shipping and Transport of Biological Materials Training Certificate. The training is valid for 2 years. The training is a federal requirement and designed to protect you, your coworkers and the public.
4. All laboratory personnel working with biological agents, rDNA, etc. must have general biosafety training and laboratory specific training, including lab SOPs and security measures for the work they are conducting.

L. Communication of Hazards to Employees and Others

Each laboratory must communicate biohazardous areas by posting appropriate signs where blood or other potentially infectious materials are being used or stored.

1. The signs and labels must be fluorescent orange or orange-red with lettering and symbols in a contrasting color: The signs and labels should look like the following:

2. A laboratory door sign with the biohazard symbol **MUST** be posted at the entrance of work areas where blood or other potentially infectious materials are being used. Door signs are available from EHS.
3. Biohazard labels must be affixed to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious materials and other containers used to store or transport blood or other potentially infectious materials unless red bags or red containers with the biohazard symbol as an integral part of the container are used.
4. Labels either must be an integral part of the container or must be affixed to the container by string, wire or adhesive or by another method preventing the loss of labels or the unintentional removal of labels.
5. Individual containers of blood or other potentially infectious materials placed in a labeled container during storage, transport, shipment or disposal are exempted from labeling requirements
6. Labels required for contaminated equipment must comply with the above labeling requirements.
7. Decontaminated regulated waste does not need to be labeled or color-coded.

M. Equipment Used in Biological Research Laboratories

1. Autoclaves
   a. Follow all manufacturer's instructions for proper use and maintenance.
   b. Avoid contact with steam.
   c. Always wear the appropriate PPE (gloves, goggles and aprons) as required.
   d. Before starting the autoclave, ensure the door is securely closed to prevent steam leaks.

e. Periodically inspect the door gasket.
f. After sterilization, wait until the chamber pressure has reached atmospheric pressure before opening the door.
g. Open the autoclave door slowly as residual steam may be present.
h. Each autoclave should be spore tested at least monthly to ensure proper temperatures and pressurizations are being achieved.

2. Biosafety Cabinets
   a. Are used for product and personnel protection and procedures generating aerosols.
   b. Enter straight into the cabinet and avoid sweeping motions while working in the cabinet.
   c. Do not place materials on the grill while working in the cabinet.
   d. Decontaminate materials before removing them from the cabinet.
   e. Biosafety cabinets must be properly disinfected before and after each use.
   f. Biosafety cabinets are certified annually to ensure proper operation.
3. Centrifuges
   a. The greatest risk with centrifugation is the creation of aerosols and leakage.
      i. Leaks can be prevented by not overfilling centrifuge tubes.
      ii. Wipe the outside of the tubes with disinfectant after they are filled and sealed.
   b. Sealed tubes, O-ring sealed rotors or O ring sealed safety buckets must be used to provide for primary containment if a risk assessment finds there is a potential for aerosol generation.
   c. Inspect tubes, lids, O-rings, buckets and rotors for damage before each use to minimize spills from broken tubes.
   d. Before use, visually inspect the load to ensure the rotor is balanced.
   e. If aerosol generation is a concern, open rotors and centrifuge tubes within a Class II biosafety cabinet.
   f. Centrifuge safety use guidelines recommend waiting 5 minutes before opening a centrifuge after a run has finished to allow aerosols to settle in the event of an unknown breakdown in containment.
   g. If a known or potential break down in containment occurred during the centrifuging process, leave the area immediately and wait at least 30 minutes to allow for dissipation of aerosols.
4. Dry Ice
5. Loop Sterilizers
   a. Sterilization of inoculating loops in an open flame generates small particle aerosols, which may contain viable microbes.
   b. Using a shielded electric incinerator (ceramic core heater) or hot bead sterilizers minimizes aerosol production during loop sterilization.
   c. Disposable plastic loops may be used for culture work where electric incinerators or gas flames are not available or recommended.
6. Microtomes and Cryostats
   a. The microtome and the cryostat are used for cutting thin sections of fixed and unfixed tissue.
   b. Laboratory use of microtomes and cryostats presents a laceration hazard in addition to generating potentially infectious aerosols.

c. Unfixed tissues should be considered capable of causing infection and should be handled using appropriate containment and PPE.

7. Open Flames in Biosafety Cabinets
   a. Open flames are not to be used within a biosafety cabinet.
   b. Open flames within a biosafety cabinet disrupt the laminar airflow, can damage HEPA filters and are a fire hazard.
8. Water Baths and Incubators
   a. Prior to use, verify equipment temperatures are appropriate for use.
   b. After use, decontaminate water baths and incubators with an appropriate disinfectant.

N. Standard Operating Procedures

a. Laboratories working with biological agents and/or biohazardous materials must develop Standard Operating Procedures (SOPs) for the activities conducted in their laboratory.
b. Each procedure must have its own SOP. Similar procedures may be grouped together under one SOP.
c. Each SOP must include the required PPE, emergency controls, workplace practices and waste disposal requirements.
d. Special approval requirement, if any.
e. Requirements for peer group review, if any.

O. Biohazard Storage

a. Biological agents and biohazardous materials should be stored in appropriate containers and labeled properly.
b. Refrigerators, freezers, cabinets and shelves used for storage of biological agents should be properly labeled.
c. Biological agents and biohazardous materials should not be left unattended when laboratory personnel are not in the laboratory.

P. Waste Handling

1. Biological/Medical waste is categorized into five (5) types defined as follows:
   a. **Type 1:** Cultures and stocks of infectious agents and associated biologicals, including laboratory waste, biological production waste, discarded live and attenuated vaccines, culture dishes, and related devices.
   b. **Type 2**: Liquid human and animal waste, including blood and blood products and body fluids, but not including urine or materials stained with blood or body fluids.
   c. **Type 3**: “Pathological Waste” such as human organs, tissues, body parts other than teeth, products of conception, and fluids removed by trauma or during surgery or autopsy or other medical procedure. This does not include animal parts.
   d. **Type 4**: “Sharps” such as needles, syringes, scalpels, and intravenous tubing with needles attached.
   e. **Type 5**: Contaminated wastes from animals that have been exposed to agents infectious to humans.
2. For disposal of biological/medical waste, the following procedures must be followed:
   a. **Type 1 and 2 Solids**

i. Store in a leak proof biohazard bag prior to decontamination.
ii. The use of a secondary leak proof container or bag is recommended.
iii. Bags shall not be filled more than three-quarters (3/4) full.

b. **Type 1 and 2 Liquids**
   i. Store in a closeable, puncture resistant container and decontaminate by autoclaving or chemically treat.
   ii. After autoclaving or chemically treating liquids, decontaminated waste can be disposed of in a sanitary sewer if no other hazardous materials are present (i.e. chemicals and/or radioactive materials).

c. **Type 3 Waste**
   i. Contact EHS for disposal information.

d. **Type 4 Waste**
   i. Place into an approved sharps container. An approved sharps container is one that is leak proof, puncture resistant, closeable, bears the biohazard symbol and is manufactured as a sharps container.
   ii. Do not clip, bend, break or recap sharps.
   iii. A sharps container must be permanently closed and disposed of through EHS when three-quarters (3/4) full.

e. **Type 5 Waste**
   i. Shall be collected in biohazard bags or other leak proof containers labeled with a biohazard sticker.

3. Biohazardous waste disposal is coordinated by EHS.

Q. Emergencies (spills, personnel exposure, utility failures, etc.)

a. If a potential exposure incident has occurred, notify the PI/Supervisor immediately and alert coworkers.
b. If biological agents or biohazardous materials enter the eyes, nose or mouth, immediately flush the contaminated area for 15 minutes with water.
c. If a needle stick or other puncture with a biological agent occurs, please seek medical attention immediately.
d. For all personnel exposures, complete the Workers' Compensation Injury Report form.
e. Clean exposed surface with the appropriate disinfecting agent for the biological agent.
f. Have plans in place to properly contain all biological agents in the event of a power outage, ventilation failure or water leak.
g. Researchers working with animals must be familiar with the Animal Welfare Disaster Plan.

VII. REFERENCES

A. U.S. Department of Health and Human Services Public Health Service
B. Centers for Disease Control and Prevention and National Institutes of Health "Biosafety in Microbiological and Biomedical Laboratories" (BMBL)
C. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines).

VIII. HISTORY

REVISION	DATE	CHANGES
0	1996	Original biosafety information incorporated into CHP.
1	2024	Formalized Biosafety Program as separate program and as part of the IBC.