SUMMARY: Faculty and students working in biological research laboratories with biohazardous materials must be aware of the potential hazards, and be trained and proficient in the practices required for handling such material safely. Each laboratory must register research with biohazardous materials and/or recombinant DNA (rDNA) with the Institutional Biosafety Committee (IBC) and must prepare a Laboratory Biosafety Manual that identifies the potential hazards that may be encountered when working with the materials.

NOTE: This guideline does not include research involving Select Agents and Toxins as defined by the U.S. Department of Health and Human Services. Refer to OSEH Guideline: CDC Select Agents for further information.

SCOPE: This Guideline focuses on procedures for safely working with biohazardous materials at Biosafety Level 2 (BL2) containment. Biohazardous materials that require Biosafety Level 3 (BL3) containment are subject to additional requirements, but must be registered and approved with the UM Institutional Biosafety Committee (IBC). No work involving Biosafety Level 4 (BL4) containment may be conducted at UM.

REFERENCE REGULATIONS: National Institute of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules Bloodborne Infectious Diseases (R 325.70001 - Michigan)

DEFINITIONS: Biohazardous Materials – Biohazardous materials are defined as materials of biological origin that may cause disease in other living organisms or cause significant impact to the environment or community. Biohazardous materials include but are not limited to:

- Viruses
- Bacteria
- Fungi
- Protozoa
- Parasites
- Rickettsia
- Prions
- Human blood, tissues, fluids, cells
- Non-human primate, and other mammalian cells and tissues
- Animals (live or tissues, cells and biological fluids from infected sources)
- Biological toxins
- Plants

*Biosafety Level 2 Containment (BL2)* - the combination of practices, equipment, and facilities applicable to clinical, diagnostic, teaching and other facilities to contain risks in which work is done with the broad spectrum of indigenous moderate-risk agents present in the community and associated with human disease of varying severity. A BL2 laboratory is suitable for work involving agents of moderate potential hazard to personnel and the environment (including plants and other animals). Refer to UM Designated Standards for UM Laboratories for detailed information on biosafety level containment. Additional BL2 practices are assigned by the IBC and OSEH based on a risk assessment of the research being conducted.

*Infectious Agents* - any material which may contain or is known to contain a causative agent of human or animal disease.

*Recombinant DNA (rDNA) Molecules* - molecules that are constructed 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. The University of Michigan requires that all recombinant DNA work be registered with the Institutional Biosafety Committee, even if it is exempt from the requirements of the NIH Guidelines for Research Involving Recombinant DNA Molecules

**RESPONSIBILITY:** Everyone working at the University of Michigan has the right to expect a safe and healthy work environment. They also have a responsibility to help assure a safe and healthy environment for themselves and others. These responsibilities are detailed in the University of Michigan Academic Laboratory and Research Safety Policy, issued jointly by the Department of Occupational Safety & Environmental Health (OSEH) and the Office of Research Ethics & Compliance (UMOR). Please click on the Policy link to view role specific responsibilities including but not limited to the following categories:
- All faculty, staff, other employees and students
- Graduate Student Research Assistants/Trainees
• Post-Doctoral Trainee/Fellow
• Laboratory Director (Faculty/Lab Manager/Supervisor
• Department Chair
• Facility Managers/Department Managers/Key Administrators/Chief Department Administrators
• Unit (School/College/Department) Safety Coordinators

Additional responsibilities specific to the implementation of this guideline follow.

Laboratory Director
Register research work involving biohazardous materials and/or rDNA with the Institutional Biosafety Committee (IBC) and ensure that approval has been granted before the initiation of the research.

Perform a risk assessment of research projects and reassess periodically as new data is obtained. The assessment should include an analysis of the risks posed by the particular organism under investigation and of any specific research, or teaching methods that affect the risk (i.e. procedures requiring highly concentrated amounts of microorganisms or inoculation of animals).

Modify and adopt the UM Laboratory Biosafety Manual which describes work practices, procedures, and policies for each laboratory to ensure that employees are protected from all potentially biohazardous materials and rDNA.

Ensure staff and students have instruction in safety procedures in research and teaching laboratories or field situations where biohazardous materials and rDNA are used or collected. Provide staff with documented formal and informal instruction and training in the practices and techniques required to ensure safety.

Inform staff and students of the risks involved with the biohazardous materials and rDNA including information pertaining to individuals who may be at a higher risk due to their immune status or pregnancy and provisions for precautionary medical practices (i.e. physical exams, serum collection, and vaccinations) as applicable.

Advise laboratory personnel of potential biohazardous materials and recombinant DNA in laboratory, precautions and actions to take in response to spills and accident, including decontamination and emergency procedures.
Review facility specific security requirements with personnel and ensure personnel are trained and equipped to follow established biosecurity procedures. *Select Agent Users should refer to the UM Institutional Biosecurity Plan for more detailed information regarding biosecurity procedures and policies.*

Ensure appropriate facility design, engineering controls and safety equipment is available.

Ensure employees are following standard laboratory practices, and select additional safety practices and procedures for employees to follow if standard laboratory practices are not sufficient to control hazard.

Maintain current knowledge to changes in international, federal and state regulations and guidelines pertaining to biohazardous materials, in consultation with OSEH-Biosafety, and modify laboratory procedures accordingly.

**Laboratory Personnel and Students**
Review all pertinent standard operating procedures and complete appropriate training prior to commencement of research involving biohazardous materials and rDNA.

Complete any required medical surveillance as mandated by the IBC or Laboratory Director and report any medical restriction, reportable illness that may result from an exposure or result in the creation of a potential hazard to the Laboratory Director.

Practice good microbiological laboratory practices and maintain knowledge of sound safety practices.

**Institutional Biosafety Committee (IBC)**
Review applications and perform comprehensive risk assessments to determine appropriateness and adequacy of containment levels and safety measures proposed and/or used in research and teaching.

Assess the adequacy of facilities, procedures, practices, training and expertise involved in research or instructional activities.

**OSEH**
Advise The Laboratory Director in matters of safety including precautions to be taken when handling biohazardous materials and rDNA.
Provide information and consultation on the operation of the laboratory to ensure compliance with all federal and state requirements to faculty, staff and students engaged in biological research

Evaluate and provide inspection of laboratory facilities for work with biohazardous materials, and rDNA.

Advise staff and students on safety measures and equipment for new procedures that may be utilized to mitigate risks associated with working with biohazardous materials and rDNA.

Provide general biosafety training related to proper handling of biohazardous materials, rDNA and maintenance of training records.

Provide advice and assistance in the event of a large high hazard or public biological material spill.

Investigate laboratory incidents, accidents, exposures, potential exposures, and illnesses that may have resulted from potential exposures to biohazardous materials and rDNA in the laboratory.

PROCEDURES:  

Registration  
All Laboratory Directors working with biohazardous materials and/or rDNA materials are required to complete and submit an application to the IBC before initiating research. **Work at the BSL2 and BSL3 levels cannot begin until approval has been granted by the IBC.** The IBC registration must be kept current to accurately reflect the materials and their manipulations, personnel handling the material, and the location in which the material may be handled or stored. The registration may be completed on-line [http://www.eresearch.umich.edu/](http://www.eresearch.umich.edu/)

Training  
All research laboratory personnel must complete OSEH BLS025 – General Laboratory Safety training on the topic of laboratory health and safety with additional focus on personal protective equipment.

All personnel working with biohazardous materials and/or rDNA must complete OSEH BLS101/101w – Biosafety and Bloodborne Pathogen Training prior to initiation of work. Employees who are classified as occupationally exposed to human derived materials
including blood, tissues, fluids, cells, and cell lines must receive this training at the time of initial assignment and annually thereafter.

Personnel who are new or entry-level lab personnel who plan to use viral vectors in vitro or in vivo, and who cannot demonstrate significant previous experience and expertise in the necessary aspects of biosafety and regulatory compliance must complete OSEH BLS008 – Working Safely with Viral Vectors.

OSEH Training classes are available for sign up on the MyLinc website.

**Biosafety Manual**
The Laboratory Biosafety Manual should include laboratory specific work practices and procedures to ensure that employees are protected from all biohazardous materials or rDNA. OSEH's web site contains a generic Laboratory Biosafety Manual that can be downloaded and modified for your laboratory. Recommendations for completing each section of the Laboratory Biosafety Manual are provided. Questions regarding implementation of the Laboratory Biosafety Manual should be referred to OSEH at (734) 647-1143.

**Note:** State and Federal regulations require an Exposure Control Plan to be maintained for work involving human derived material

**Inspections**
Biosafety laboratory inspections are a requirement for all research activities involving BL2 containment. The goal of the inspection is to facilitate the safe conduct of research involving biohazardous materials, to maintain safe working conditions by eliminating or mitigating risks of exposure and to ensure compliance with federal and state regulations. All biosafety laboratory inspections will be conducted on an annual basis and will be scheduled in advance whenever possible. Unannounced and follow up inspections may be conducted as necessary. Following the completion of the inspection, a summary and recommendations will be provided to the laboratory. The OSEH Biosafety Inspection Checklist will be used during the inspection. Laboratory personnel should use this checklist to identify safety and regulatory deficiencies and address them before their inspection occurs.
Laboratories that register with the IBC and intend to conduct work under BL2 containment must have satisfactorily completed a Biosafety Lab Inspection prior to obtaining approval from the IBC. Inspections will be conducted annually for all laboratories.

Laboratory inspections may also be required as part of the research granting agency’s stipulations. For example, certain Department of Defense (DOD) grants and/or contracts require the institution to provide assurance that the laboratory is inspected on certain schedules.

Additionally, laboratory inspections may be required prior to setting up accounts and receiving biological specimens from certain vendors/institutions. The vendors or organizations require that the institution provide assurance for the safe use and disposal of the material prior to their shipment. These include ATCC, BEI Resources, national repositories or private organizations etc. The vendors or organizations require that the institution provide assurance for the safe use and disposal of the agent prior to shipment.

Door Signs and Labels
OSEH requires that all laboratories have a door sign posted on the outer entrance where biohazardous materials are used. A 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 Laboratory Director to facilitate contact in case of emergency.

To obtain a door sign, complete the online request form or contact OSEH at (734) 647-3133.

A biohazard warning label, incorporating the universal biohazard symbol will be placed on all laboratory equipment where biohazardous materials are stored (i.e. freezers, refrigerators, incubators, etc.).

Personal Protective Equipment (PPE)
PPE is worn to prevent contact with biohazardous materials with mucuous membranes of the eyes, nose, mouth and/or non-intact or abraded skin which could serve as points of entry. Appropriate PPE for the laboratory may include gloves, safety glasses, safety goggles, face shields and laboratory coats. The minimum level of protective equipment in any lab should include lab coats, safety
glasses and appropriate gloves. Specific PPE requirements are determined by the risk assessment of the research.

**Accidents, Exposures, and Spill Response**
Laboratory-specific SOPs should address any emergency response procedures, including those required if an accident, exposure, potential exposure, or an illness that may have resulted from a possible laboratory exposure, release from primary containment or environmental contamination of any biohazardous material.

**Spill and Exposure Response Procedures**
An exposure incident is a specific eye, mouth, other mucous membrane, non-intact skin or parenteral contact with biohazardous materials that results from the performance of an employee’s duties or commission of the person’s responsibilities in conjunction with the research or educational mission. A person who sustains a known or potential exposure incident must remove their gloves and treat the affected area immediately by following the appropriate exposure incident response. Refer to the OSEH Injuries and Exposures poster for further information. Obtain immediate medical attention at UM Occupational Health Services (OHS) or the UM Emergency Department.

**IMPORTANT:** Report all exposures, injuries, spills and near-miss incidents involving biohazardous materials and recombinant DNA to the following:

- **Laboratory Director** (as soon as practical)
- OSEH-Biosafety (734) 763-1143 (as soon as practical)
- **Work~Connections** (complete Illness and Injury Form within 24 hours)
- Complete **OSEH Incident and Near-Miss Report Form**

**Lab Commissioning, Lab Decommissioning and Lab Moves**
To ensure appropriate containment is maintained, safety measures are implemented and compliance with all federal, state, and local regulations and guidelines for biohazardous materials have been met, documentation must be provided, reviewed, and approved by the IBC before starting research with any biohazardous materials or rDNA in a new facility. This includes materials which may be brought to campus by incoming new faculty or materials that may be moved to new locations not previously authorized as part of the LABORATORY DIRECTOR’s IBC approved protocol. Refer to the OSEH Laboratory Commissioning Guideline for further information.
To ensure that the biohazardous materials and rDNA are properly removed and facilities are decontaminated before the closing of a lab, The Laboratory Director must contact OSEH prior to moving biological agents when closing out a lab. Refer to the OSEH Laboratory Decommissioning guideline for additional information.

RELATED DOCUMENTS:
- Biosafety in Microbiological and Biomedical Laboratories, HHS, CDC/NIH publication
- OSEH Biohazardous (Medical) Waste Disposal
- Exposure Control Plan – Bloodborne Pathogens

TECHNICAL SUPPORT: All referenced guidelines, regulations, and other documents are available at OSEH (734) 763-1143