

## Chapter 1 – INTRODUCTION

This chapter contains general information about the University of Missouri (MU) Biosafety Program. Of particular interest in this chapter are biosafety program purpose, biohazardous material definition, biosafety program goals, campus policies, and roles and responsibilities.

### 1.1 Manual Purpose

The Biosafety Manual presents the MU Biosafety Program, which is designed to protect students, faculty, staff, and the public from potential adverse exposure to biohazardous material used in MU research and teaching activities.

### 1.2 Biohazardous Material Definition

The MU Biosafety Program applies to all research involving recombinant or synthetic nucleic acid molecules and research requiring Biosafety Level 2 (BSL-2) or higher containment research activities (see [Section 2.4](#)). Currently, BSL-4 research activities are not allowed at MU. Biohazardous materials are any microorganism, or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing: 1) death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; 2) deterioration of food, water, equipment, supplies, or material of any kind; or 3) harmful alteration of the environment. These include, but are not limited to:

- Certain bacteria, fungi, viruses, rickettsiae, spirochetes, protozoa, parasites
- Recombinant or synthetically derived nucleic acid molecules
- Listed Select Agents & Toxins (exempt & non-exempt quantities)
- Cultured human or animal cells and the potentially infectious agents these cells may contain
- Viroids and prions
- Other infectious agents as outlined in laws, regulations, or guidelines.

Examples include all materials containing recombinant or synthetically derived nucleic acid molecules; transgenic animals or plants; human, animal or plant pathogens; human blood/tissue and certain human body fluids; select agents and toxins; high consequence livestock pathogens and toxins; and human or monkey cell cultures. Specifically excluded are non-recombinant or synthetically derived nucleic acid molecules and BSL-1 containment research activities.

### 1.3 MU Biosafety Program

Biosafety is a complete program of recognition, evaluation, and control to minimize the health risk to students, faculty, staff, and the public from potential exposure to biohazardous materials that are used in the research and teaching activities at MU. To be effective this program needs the active participation of faculty, staff and student. The Biosafety Program is designed to:

- Enhance biosafety knowledge for MU Faculty, Staff, and Students.
- Assist researchers in protecting personnel, the environment and property from exposure.
- Provide the process and tools to assess safety needs and precautions for emergency response, planning, initiation, and termination of activity involving biohazardous materials.

The goals of the Biosafety Program are:

- Protect personnel from exposure to infectious agents.
- Prevent environmental contamination.
- Provide an environment for high quality research while maintaining a safe work place.
- Comply with applicable federal, state, and local requirements.

The Biosafety Section of Environmental Health and Safety (EHS) administers the MU Biosafety Program. Our mission is to work with the campus community to develop and implement an efficient, convenient, comprehensive, and forward-looking biosafety program. The campus has an Institutional Biosafety Committee (IBC) to provide oversight of the program. Additional MU Biosafety Program information is available on the EHS Website <https://ehs.missouri.edu/>

## 1.4 Campus Policies

Section 7:050 of the [Business Policies and Procedures Manual](#) of the University of Missouri-Columbia states:

- The management of environmental hazards, including transportation and use of all hazardous materials and the proper treatment and/or disposal of hazardous waste generated through University research, academic, and service and support staff operations, must comply with the provisions of applicable Federal and State statutes and their associated rules and regulations.
- Faculty members, students, and other University employees are responsible for being informed of the applicable rules and regulations and to comply with these rules and regulations. The University will make every appropriate effort to protect faculty members and other employees from civil penalties imposed by outside agencies as a result of the alleged improper use, storage, or waste management practices provided they have made bona fide efforts to comply with appropriate regulations.
- Non-Compliance—Non-compliance with Federal and/or State statutes and their associated regulations can result in significant penalties and fines to the University and to its employees as individuals. Failure to comply with the applicable rules and regulations constitutes possible grounds for dismissal of students and termination for cause of faculty and staff.

Other applicable policies in the *Business Policies and Procedure Manual* of the University of Missouri-Columbia are as follows:

### **HEALTH & SAFETY**

[7:001 MU Environmental Health and Safety Policy](#)

[7:010 Emergency Procedures](#)

[7:020 Occupational Health & Safety](#)

[7:030 Personal Protective Equipment](#)

[7:040 Preparing Hazardous Packages](#)

[7:050 Hazardous Materials & Waste](#)

[7:060 Biohazard Disposal](#)

## 1.5 Roles and Responsibilities

For the purposes of the MU Biosafety Program, the campus community is divided into six categories for roles and responsibilities. Individuals may fall into more than one of these categories:

- Principal Investigators and Supervisors (Registered Users)
- Biohazard Workers

- Ancillary Workers (Non-Biohazard Qualified Personnel)
- Deans, Directors, Administrators, and Department Heads
- Environmental Health and Safety
- MU Institutional Biosafety Committee (IBC)

### 1.5.1 Principal Investigators and Supervisors (Registered Users)

Principal investigators and supervisors (Registered Users) have primary responsibility for safety when work is conducted with biohazardous materials. Their responsibilities include:

- Submit the initial protocol and any subsequent changes to the IBC for review and approval prior to initiating recombinant or synthetically derived nucleic acid molecule or Biosafety Level 2 or 3 containment research activities ([Section 3.1](#)).
- Submit renewal protocol application forms to EHS of locations where recombinant or synthetically derived nucleic acid molecule or Biosafety Level 2 or 3 containment research activities are conducted ([Section 3.2](#)).
- Complete annual protocol survey process for all recombinant or synthetically derived nucleic acid molecule or Biosafety Level 2 or 3 containment research activities ([Section 3.1](#)).
- Report any newly identified select agents and toxins, high consequence livestock pathogens and plant pathogens immediately to EHS ([Section 3.1](#), [Section 4.3.9](#)).
- Notify EHS of all persons who use biohazardous material in their work location and ensure these persons receive appropriate training ([Chapter 2](#)).
- Attend the Introduction to Biosafety training course and the Biosafety Refresher course a minimum of every three years thereafter ([Chapter 2](#)) for research activities requiring Biosafety Level 2 or 3 containment research activities.
- Attend the Recombinant DNA online training initially and a minimum of every three years thereafter for BSL 1 laboratories involved in work with recombinant or synthetically derived nucleic acid molecules. ([Chapter 2](#)).
- Complete laboratory staff and animal care personnel initial enrollment and annual review/update of MU OHSP. Assure staff are aware of medical surveillance options and assess potential medical predisposition to animal or laboratory related health risks.
- Maintain a current and up-to-date inventory of biohazardous material ([Section 4.3.6](#)).
- Complete and post appropriate biohazard signs, labels ([Section 4.3.8](#)) and Emergency Notification Signage ([Appendix B](#)).
- Request collection of Biohazardous Unwanted Materials in a timely manner ([Chapter 5](#)).
- Ensure availability of reference information on biological hazards, and ensure that all staff understands how to use these references ([Chapter 2](#)).
- Conduct risk assessments of each task involving biohazardous material. Assess risks in order to set the biosafety containment level for the proposed work. Make an initial determination of the required levels of physical and biological containment in accordance with the MU Biosafety Manual; select appropriate microbiological practices and laboratory techniques to be used for the research; assure precautions are taken ([Chapter 4](#)).
- Ensure that all workers under their supervision use proper Personal Protective Equipment ([Section 4.3.2](#)).
- Understand the proper procedures to use in the event of a release or other emergency ([Chapter 6](#)).
- Work with EHS monitoring personnel to maintain safe work areas in compliance with MU policies and government regulations.
- Comply with transport and shipping requirements for recombinant or synthetic nucleic acid molecules and biohazardous materials ([Chapter 7](#)).
- Control Ancillary Worker access to areas where biological hazards may be present ([Chapter 4](#)).

- Complete proper Biohazardous Materials Laboratory Closure prior to termination of work with biohazardous materials ([Section 5.3](#)).
- Report to EHS all significant violations, releases, spills, injuries or illnesses related to biohazardous materials use. Evaluate and correct work errors and conditions.

### 1.5.2 Biohazard Workers

Biohazard Workers are persons who work under the supervision of a Principal Investigator or Supervisor (Registered User). Most of these employees work with biohazardous materials on a daily basis. Their responsibilities include:

- Attend the Introduction to Biosafety training course and then the Biosafety Refresher in-person or online course a minimum of every three years thereafter for BSL 2/3 Laboratories ([Chapter 2](#)).
- Attend the Recombinant DNA online training initially and a minimum of every three years thereafter for BSL 1 laboratories involved in work with recombinant or synthetically derived nucleic acid molecules. ([Chapter 2](#)).
- Attend the Category B, Genetically Modified Organisms, and Patient Specimens online training initially and a minimum of every two years thereafter ([Chapter 2](#)).
- Attend the Category A Shipping training initially and a minimum of every two years thereafter if applicable ([Chapter 2](#)).
- Report promptly all accidents, biohazard exposures, work (or possibly work) related illnesses, hazardous circumstances and incidents to their supervisor ([Chapter 6](#)).
- Know and follow all proper protocols and procedures for acquisition, use, storage, and disposal of biohazardous materials ([Chapter 3](#)).
- Know where to find and how to properly use reference information and resources on biohazardous materials ([Chapter 2](#)).
- Know how to respond to releases and other emergencies involving biohazardous materials ([Chapter 6](#)).
- Be familiar with and use Personal Protective Equipment needed for safety ([Section 4.3.2](#)).
- Work with EHS monitoring personnel to maintain safe work areas that comply with MU policies and government regulations.
- Enroll in MU Occupational Health & Safety Program (OHSP) if job requirements may result in contact with or exposure to animals, animal tissues/fluids, human cells/tissues/fluids, human bloodborne or zoonotic pathogens.

### 1.5.3 Ancillary workers (non-biohazard qualified personnel)

Ancillary Workers are persons who work in areas containing biohazardous materials, but who do not normally work directly with these biohazardous materials. Examples of Ancillary Workers are custodial staff, ITS, maintenance staff, delivery and visiting/contract personnel, and police officers. Their responsibilities are as follows:

- Recommend attending Ancillary Worker Biosafety training course and subsequent refresher training a minimum of every three years thereafter.
- Take precautions to avoid disturbing biohazardous materials.
- Report releases and other unsafe conditions involving biohazardous materials to their supervisor.
- As directed use proper Personal Protective Equipment needed for safety.
- Request assistance from Supervisor or EHS when uncertain about risks related to biohazardous materials.

### 1.5.4 Deans, Directors, Administrators, and Department Heads

Deans, Directors, Administrators, and Department heads have the following responsibilities:

- Be familiar with, provide safety leadership, and ensure compliance regarding NIH, CDC, MU IBC and Biosafety program guidelines.
- Assure health surveillance program is maintained for personnel engaged in research for the campus community.
- Assist in data collection of all significant violations, releases, spills, injuries or illnesses related to biohazardous materials use and assure information is reported to NIH by EHS.
- Complete and submit NIH annual report.
- Assist EHS in communicating major announcements and identifying appropriate personnel for Registered User status.
- Review EHS Biosafety inspections to assist in resolving problem situations.
- Identify funding sources when needed to correct safety hazards and ensure that appropriate facilities are available to control biohazards.
- Assure that the Principal Investigator and all personnel have necessary training.
- Assure proper laboratory closure is completed prior to termination of biohazardous material use or storage.

### **1.5.5 Environmental Health & Safety (EHS)**

Environmental Health and Safety is the campus administrative unit that oversees the Biosafety Program. Specific responsibilities of EHS include:

- Develop safety and security guidelines for the campus community so that biohazardous materials are used in compliance with government regulations.
- Maintain databases of information related to the MU Biosafety program.
- Provide or arrange appropriate training programs and staff to meet the IBC and campus community needs.
- Periodic monitoring of areas where biohazardous materials are used or stored to assure that program guidelines are met.
- Advise and assist the campus community on biosafety matters such as emergency response, personnel contamination, investigation of incidents and reporting.
- Collect and dispose of biohazardous Unwanted Materials in an environmentally sound and cost-effective manner.
- Assist in arrangement for the proper shipping and transportation of biohazardous materials.
- Serve as the liaison with regulatory agencies such as Center of Disease Control and Prevention, National Institutes of Health, Department of Transportation, and Department of Agriculture.

### **1.5.6 Institutional Biosafety Committee (IBC)**

The MU Institutional Biosafety Committee is appointed by the Office of Research to oversee the campus Biosafety program. Specific responsibilities of the committee include:

- Review, recommend and approve policies and guidelines that ensure biosafety procedures, equipment, facilities, and training are appropriate for the biohazard risk.
- Review and approve all recombinant or synthetically derived nucleic acid molecule research and/or biohazardous materials requiring containment at Biosafety Level 1, 2 or 3.

- Review Biosafety staff laboratory monitoring of Principal Investigators (Registered Users) and assist in resolving problems.
- Provide a campus forum for addressing issues involving biohazardous materials.

## **1.6 Related Environmental Health and Safety Programs**

EHS provides leadership in working with the campus community to provide a safe and healthful environment. This is our contribution to the University's mission of teaching, research and public outreach.

This manual focuses on biohazardous materials. EHS offers training and guidance on a variety of issues that pose potential hazards to people and the environment. These issues include, but are not limited to:

- Chemical Safety
- Environmental Issues
- Fire Safety
- Food Safety
- Hazardous Materials
- Personal Protection
- Radiation Safety
- Workplace Safety

For further information about these programs, contact EHS at 882-7018.