

**UNIVERSITY OF LOUISIANA AT MONROE
POLICIES AND PROCEDURES MEMORANDUM**

<i>Title:</i>	BIOSAFETY COMPLIANCE
<i>Effective Date:</i>	7/1/2009
<i>Update Responsibility:</i>	Academic Affairs
<i>Update Date:</i>	NONE
<i>Cancellation Date:</i>	NONE

1) PURPOSE/PREAMBLE

This policy serves as guidance for proposing, approving, handling, storage, disposal, and documenting biosafety compliance. The University of Louisiana at Monroe (ULM) expects compliance with the provisions of this policy to ensure a safe working environment exists that provides protection to ULM's employees and the community at large. In turn, the Institutional Biosafety Committee (IBC) is charged with the oversight of recombinant DNA, pathogens, toxins, toxicants and carcinogens and to ensure that ULM complies with all federal and state regulations.

All ULM research and instructional activities that involve biohazardous materials shall be reviewed and approved by the IBC prior to the use of any such reagent. In order to capture the necessary information for compliance, yet not burden the ULM community, two reporting vehicles are available. Department Biosafety Form captures the biosafety information for the upcoming semester and is submitted by the Department Head for the entire instructional related activities. The Biosafety Protocol Form is to be used by Principal Investigators (PI) for research activities.

The request should be submitted to the Office of Sponsored Programs and Research (OPSR), which assists the IBC with the administrative aspects of biosafety compliance. The IBC has the right and authority to monitor the use of biohazardous material.

2) DEFINITIONS

- a. Biohazardous Material The categories below represent the areas of concern with respect to biosafety. Projects involving material(s) included by any of these categories must follow the established procedures to obtain IBC approval.
 - i. When using Chemical Carcinogens.
 - ii. When using Toxins produced by living organisms.
 - iii. When using Oncogenic viruses.
 - iv. Infectious agents requiring handling conditions above Biosafety Level-1. (as determined by CDC-NIH)
 - v. When using recombinant DNA.
 - vi. When using Human blood and blood products, human body fluids, and/or human tissue.
 - vii. Whenever a contractual agreement or grant proposal requires IBC approval for the safe handling of a biological or chemical product.
 - viii. HHS and USDA Select Agents and Toxins, as defined in Federal Regulations 7CFR331, 9CFR121, and 42CFR73, Additional Requirements for Facilities Transferring or Receiving Select Agents, Public Law 107-188, Public Health Security and Bioterrorism Response Act.
 - ix. USDA Restricted Animal Pathogens, as determined by the United States Department of Agriculture (USDA).
 - x. Any research that requires a permit from USDA Animal and Plant Health Inspection Service (APHIS).
 - xi. When using Wild Poliovirus or materials that may contain wild poliovirus.
- b. Biosafety Level (BL)* refers to a description of the degree of physical containment being employed to confine organisms containing recombinant DNA molecules and to reduce the potential for exposure of laboratory workers, persons outside of the laboratory, and the environment.

- c. Biological Safety Officer (BSO)* refers to an individual appointed by an institution to oversee management of biosafety risks. The NIH Guidelines require that a BSO be appointed when the institution is engaged in large-scale research or production activities, or in research requiring containment at BL-3. Research requiring BL-4 is strictly prohibited.
- d. Carcinogens/hazardous chemicals refer to any substance that is an agent directly involved in the promotion of cancer or in the increase of its propagation or considered hazardous and requires special training and disposal.
- e. Infectious agents refers to an agent that is capable of causing an infection i.e. polio virus.
- f. Institutional Biosafety Committee refers to ULM's institutional authority and regulator on matters concerning biohazardous materials.
- g. Principal Investigator (PI) refers to ULM faculty or staff member directly responsible for the project or program that will utilize the biohazardous materials.
- h. Recombinant DNA molecules* refers to molecules constructed outside of living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or molecules that result from their replication.
- i. Reproductive toxins refer to chemicals that can damage the reproductive systems of both men and women. Exposure to these agents before conception can produce a wide range of adverse effects including reduced fertility etc.
- j. Select agents/toxins (e.g. Ebola, anthrax) refer to agents that US Department of Health and Human Services considers to have the potential to pose a severe threat to human health. A list of these agents is found in the select agent regulation (42 CFR 73).

* These definitions are from NIH's Office of Biotechnology Activities

3) RESPONSIBILITIES

Principal Investigator/Instructor

- i. Understand ULM's biosafety policy and procedures through the completion of ULM's biosafety training program.
 - ii. Ensure that the proper training of students working with biohazardous materials occurs
 - iii. File a revised protocol should any previous approved information change
 - iv. Report all incidents to OSPR and ULM's Environmental Safety Officer
 - v. Secure IBC approval in advance to using any biohazardous materials
 - vi. Secure the Department Chair and/or Dean's approvals according to college procedures
 - vii. Forward completed packet to the Office of Sponsored Programs and Research
- b. Department Chair
- i. Ensure that all department employees are aware of the policy and procedures
 - ii. Ensure that all appropriate college personnel receive the necessary training
 - iii. File a Department Biosafety Form at least 20 business days (4 weeks) prior to the semesters
 - iv. File a revised protocol should any previous approved information change
 - v. Report all incidents to OSPR and ULM's Environmental Safety Officer
 - vi. Review and approve biosafety requests
- c. Dean
- i. Ensure that all department heads are aware of the policy and procedures
 - ii. Ensure that all department heads uphold safety standards
 - iii. Ensure that all appropriate college personnel receive the required training
- d. Office of Sponsored Programs and Research
- i. Log in protocol
 - ii. Scan protocol and forward the request to the IBC Chair
 - iii. After the IBC makes a determination on a protocol
 - (1) Enter information into database
 - (2) Notify principal investigator/instructor of the determination
 - (3) File in the designated secure compliance cabinet
 - (4) Manage the renewal notification system

4) Potential Consequences

- a. A list of NIH specific potential consequences may be found at OSPR's research compliance webpage. PIs, department heads, deans, administrators, coordinators, faculty and staff should remember the following potential consequences of biosafety noncompliance:
 - i. Suspension of research and lab access until completed retraining on all appropriate modules
 - ii. Return funds to the sponsor for improperly use of rDNA/biohazardous materials
 - iii. Repay ULM for the levied fines and/or penalties for clean up
 - iv. Reporting noncompliance to the federal Office of Biotechnology Activities
- b. Unauthorized use of biohazardous materials may be subject to disciplinary action and/or dismissal.

Policy References:

Research Administration and Management. [edited by] Elliott C. Kulakowski and Lynne U. Chronister. Jones and Bartlett Publishers. Sudbury, MA. 2006.

National Institutes of Health (NIH)'s Office of Biotechnology Activities <http://oba.od.nih.gov/oba/index.html>

Review Process:

Academic Affairs
Academic Deans

Distribution:

Academic Deans
Executive Cabinet
Institutional Safety Officer