Biological Safety Regulation

REG12.60.01 Current Version

Authority: Chancellor

History: First enacted 1992; last revised October 4, 2010; Placed in University Policy Manual after EXPEDITED REVIEW, transitioned without substantive change from prior version, January 29, 2013.

Related Policies: ECU Infection Control Regulation

Related Materials: ECU BioSafety manual

Additional Resources: Biological Safety Program 74FR 48275
OSHA Blood Borne Pathogens 29CFR 1910.1030
OSHA Respiratory Protection Program 29CFR1910.134
IATA/DOT/FAA Shipping 42CFR parts 171-178
DOT Biomedical Waste 49CFR 171-178
Select Agent Act 42CFR73.16
NIH Guidelines for Research Involving Recombinant DNA Molecules 2002
Biological Safety in Microbiological and Biomedical Laboratories (BMBL), CDC, 2007

WHO 2006

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1. Introduction

East Carolina University is committed to maintaining a workplace and learning environment free of recognized hazards while allowing for use of a wide variety of biological and biohazardous materials in teaching and research laboratories following accepted safety practices and containment procedures. The Biological Safety Program is established

to ensure these goals.

2. Definitions

2.1. Biosafety: Laboratory biosafety includes all containment principles, techniques, equipment and practices that are implemented to prevent the unintentional exposure to biological agents and toxins, or other accidental release (WHO/CDS/EPR, 2006).

2.2. Biological Agents:

2.2.1. Any microorganism (including those which have been genetically modified), genetic elements of microorganisms, materials containing or derived from microorganisms (including prions, cultures, parasites); or biological materials (e.g., toxins, allergens), which may cause an infection, create or provoke an immune reaction or elicit a toxic or allergic response in humans, animals, or plants or have an adverse effect on the environment.

2.2.2. Recombinant DNA molecules, DNA or RNA derived from recombinant organisms or DNA, any organisms, microorganisms or viruses containing recombinant DNA (including plants and animals), or nucleic acid components subject to NIH requirements.

2.2.3. Human blood, serum or body fluids defined as potentially infectious for human blood borne pathogens, including unfixed human tissue and human cell lines.

2.3. Biohazard: A Biological agent is considered to be biohazardous if exposure may be a hazard to laboratory workers, laboratory animals or livestock, the community, or the general environment (WHO). Biohazardous agents include, but are not limited to conventional pathogens, recombinant DNA/RNA molecules and recombinant organisms; human body fluids, tissues or cell cultures; indigenous or experimental infections of laboratory animals or plants; toxins elaborated by plants, animals or microorganisms. Whether an agent is considered a Biohazard varies with the actual conditions of use by a specific laboratory, volumes of material used and manipulations performed, the current state of the science, and current regulatory agency expectations or authoritative agency interpretations.

3. Biological Safety

3.1. Purpose: All work performed at East Carolina University which involves biohazardous and biological agents will be conducted in a manner which affords adequate protection to the wellbeing of personnel, (Faculty, staff, students, visitors, contract workers), the immediate environment surrounding community and the general environment or ecosystem.

3.2. Scope: The work of all laboratories using biological material of greater than minimal risk (Biosafety Level 1 as defined by BMBL) and all use of recombinant materials, techniques or organisms is subject to

review.
3.2.1. A Biological Safety registration for each biohazardous agent used in the laboratory will be completed by the Principal Investigator and submitted for review by the Biological Safety Committee.
3.2.2. All faculty, staff, students or visitors to these laboratories will follow the requirements outlined in the approved BioSafety registration, under the direction of the Principal Investigator.
3.2.3. All work conducted at facilities owned, leased or controlled by the University will be conducted in accord with this regulation and the procedural details outlined in the Biosafety Manual.
3.3. The University Biological Safety program is established to ensure that adequate administrative, physical, and operational protective measures are in place in order to:
3.3.1. Protect faculty, staff, students and visitors from biological agents that are stored, used handled or disposed at or by the University.
3.3.2. Reduce the risk of unintentional release of biological agents and toxins, including the risks of infection, exposure, environmental contamination or adverse impact.
3.3.3. Comply with all regulatory and other legal requirements applicable to the biological agents, materials and biotoxins that are used, stored or handled.
4. Process and Structure The ECU Biological Safety Program is comprised of the Institutional Biological Safety Committee and the Biological Safety section of the Office of Prospective Health.
4.1. The Biological Safety section Office of Prospective Health, includes technical and administrative personnel who oversee, implement and enforce the program on a day to day basis. The Biological Safety Officers have responsibility and operational authority to assist with the safe use of biological agents, ensure compliance, and interface with regulatory agencies.
4.2. The Biological Safety Committee (a.k.a. Institutional Biological Safety Committee) is authorized to review, and approve all research projects using infectious or biohazardous agents, provide input and oversight of teaching or research laboratory activities utilizing biohazardous agents, determine the applicable BioSafety level and practices governing the safe conduct of the work, and review problems and recommend corrective actions.
4.2.1. The Committee is comprised of faculty and staff members representing multiple departments with experience using biological agents from across the entire campus and from the community.
4.2.1.1. The Committee is headed by a faculty member from Department of Microbiology and Immunology or another department with relevant expertise and experience.

4.2.2. This committee is required in order for the University to be eligible to receive any grants funded by National Institutes of Health (NIH).
4.3. Authority: Where unsafe practices, conditions immediately dangerous to life or health, or other actions in violation of established regulations, guidelines or ECU BioSafety standards are observed, the Biological Safety Officer is authorized to suspend the work until a thorough review can be made by the Institutional Biological Safety Committee and until biosafety procedures satisfactory to the committee are adopted.
4.3.1. Biological Safety will report adverse events to federal or state authorities as required.
5. The BioSafety Manual provides detailed information on the specific practices, procedures, physical and engineering controls and protective equipment to be followed. The manual:
5.1. Provides guidance for laboratories and individuals using Biological Materials or Select Agents and provides the Principle Investigator with reference materials and links to develop project-specific Biological Safety standard operating procedures,
5.1.1. Specifies the training required by all individuals working with these agents,
5.1.2. Serves as the Exposure Control Plan for Bloodborne Pathogens in research with human materials,
5.1.3. Outlines the proper handling, treatment and disposal of biohazardous wastes,
5.1.4. Describes the steps to be taken in the case of spills or other emergencies,
5.1.5. Prescribes any requirements for medical preventive and surveillance procedures,
5.1.6. Outlines the responsibilities of all parties involved in obtaining and using biohazardous agents.
5.2. The content of the manual is updated whenever applicable regulations or national standards change or are re-interpreted by authoritative agencies, to reflect current best practices and advisories, and to clarify administrative processes and procedures.
5.2.1. Changes to the BioSafety Manual will be initiated by the Biological Safety Section, reviewed and approved by the Institutional Biological Safety Committee and posted online.
6. References
6.1. The current NIH Guidelines for Use of Recombinant DNA, and their most recent interpretations, will be used to guide all research conducted at ECU, regardless of funding source.
6.2. The current BMBL serves as a national standard for BioSafety

and the basic guideline for work with microorganisms and toxins. The principles of the BMBL are reflected in the BioSafety Manual.