

Institutional Handbook of Operating Procedures Policy 08.01.10	
Section: Research, Regulations and Compliance	Responsible Associate Vice President: Research Regulations and Compliance
Subject: Biosafety Training	Responsible Entity: Department of Biosafety

I. Title
Biosafety Training

II. Policy

A. This policy provides requirements for initial and ongoing required training for the University of Texas Medical Branch (UTMB) students and workforce which includes: faculty, staff, students, volunteers, and select contractors of UTMB. All faculty, staff, students, and select contract workers shall participate in and complete training applicable to their work environment and employment duties.

Biosafety training is provided to improve safe practices at UTMB, increase biosafety awareness in work areas, and meet requirements set forth by National Institutes of Health (NIH), U.S. Federal Select Agent Program (FSAP), and other applicable federal and local regulations or guidance, as well as UTMB policies and procedures.

B. Biosafety training is required for individuals when a job role meets one of the following:

1. handling of biological materials or recombinant or synthetic nucleic acids (r/sNA) that are regulated by the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)
2. entrance into areas where biological materials are stored or utilized, or
3. supervisors of those handling biological materials or NIH Guidelines-regulated r/sNA, or of those entering areas where biological materials are stored or utilized.

III. Procedures

A. Required Training. Required training includes, but is not limited to:

1. New Employee Training
 - a. New employees, re-hire employees, volunteers, and select contractors shall complete assigned biosafety training within 30 days of hire.
 - b. Students who are also employees shall complete assigned biosafety training concurrent with when their job role falls under the requirements defined above.
 - c. Employees that transfer within UTMB shall complete assigned biosafety training within 30 days of transfer.
2. Annual Training

- a. All UTMB students and workforce are required to complete Annual Biosafety Refresher Training if their job role still falls under the requirements defined above.
 - b. Additional annual Department of Biosafety training may be required for specific job roles, tasks, or to maintain access to areas where biological materials are stored or utilized.
3. Departmental Training
- a. Training provided by the Department of Biosafety is required for specific job roles, tasks, and/or access relating to areas where biological materials are stored or utilized.

B. Training Documentation Criteria

1. Documentation of training shall be kept for each employee, faculty, student, and contract worker. Training documentation shall contain:
 - a. name of trainee
 - b. date of training
 - c. title of training

C. Monitoring Compliance

1. Compliance with this policy shall be monitored by the following UTMB committees:
 - a. The Institutional Biosafety Committee (IBC)
 - b. The Institutional Animal Care and Use Committee (IACUC)

IV. Definitions

A **biological agent** is any microbiological entity, cellular or non-cellular, naturally occurring or engineered, capable of replication or of transferring genetic material that may be able to provide infection, allergy, toxicity or other adverse effects in humans, animals, or plants. This includes bacteria, fungi, viruses, viroids, endoparasites, exoparasites, and prions.

Biological materials are any material comprised of, containing, or that may contain biological agents and/or their harmful products. This includes blood, secretions, or tissues of human or animal origin. Animals and plants or parts thereof handled in relevant laboratories that may contain biological agents or toxins or biological agent vectors, such as arthropods, nematodes, and mites, are considered biological materials.

Recombinant and synthetic nucleic acids (r/sNA) are:

1. molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids;
2. nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or
3. molecules that result from the replication of those described in 1) or 2) above.

V. Relevant Federal and State Statutes

[National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules \(NIH Guidelines\)](#)

[Federal Select Agent Regulations Governing the Possession, Use, and Transfer of Select Agents and Toxins](#)

VI. Related Guidance

Occupational Safety and Health Administration (OSHA) [Bloodborne Pathogens \(BBP\) Standard](#)

VII. Related UTMB Policies and Procedures

IHOP 03.05.05 – [Mandatory Education and Training for UTMB Workforce and UTMB Students](#)

VIII. References

[Biosafety in Microbiological and Biomedical Laboratories \(BMBL\), current edition - Centers for Disease Control \(CDC\) and National Institutes of Health \(NIH\)](#)

ISO 35001:2019 Biorisk Management for Laboratories and Other Related Organizations

IX. Dates Approved or Amended

Include origination date, dates of major or minor revisions and dates reviewed without changes.

<i>Originated: 7/30/2024</i>	
<i>Reviewed with Changes</i>	<i>Reviewed without Changes</i>

X. Contact Information

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