



HMS Primary Responsible Office: Office of Biological Safety

Approval Body: Committee on Microbiological Safety (COMS)

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COMS Training Policy

I. Purpose

The purpose of this policy is to provide the requirements for training to all personnel working on a COMS registered protocol.

II. Applicability and Minimum Guidelines

- A. All personnel (PI and staff) working on an active COMS protocol registration must meet all regulatory and institutionally mandated training requirements pertaining to COMS-Regulated Materials (CRM).
- B. All PIs registered with COMS must complete PI compliance or equivalent training that covers applicable federal, state and local regulations prior to initiation of recombinant and synthetic nucleic acids work while research under COMS is on-going.
- C. An initial awareness-level training on the NIH Guidelines must be provided to PIs that do not work with recombinant and synthetic nucleic acids. Should PIs begin work with recombinant and synthetic nucleic acids at any point, they will then be required to complete the training.
- D. All laboratory staff working on a COMS protocol must be listed as personnel on a COMS protocol - and complete general EH&S biosafety training and agent-specific biosafety training prior to beginning work with biological materials. Agent-specific training may be performed by the PI or by a knowledgeable designee. Biosafety training must be completed prior to initiation of work, when hazards of the work change, and as per regulatory/institutional requirements, but not less frequently than once every three years.

III. Record Keeping Requirement:

Each institution maintains documentation of training for laboratories under COMS purview per institutional policy and regulatory requirements pertaining to the research.

IV. Implementation procedures

A. Monitoring Compliance and Sanctions for Non-compliance:

1. Each institution shall verify PI training at the time of COMS protocol submission and laboratory inspection.
2. At the time of submittal of a COMS new protocol, amendment, or renewal, the PI or their designee will verify that the PI and study staff listed on the protocol have taken the required biosafety training. EHS will also verify if new staff members have completed trainings during laboratory inspections.
3. Untrained individuals will be prohibited from working on COMS protocols until required training is completed.
4. COMS protocol(s) will be suspended if any training non-compliance is not corrected within the 30-day period.

B. COMS Responsibilities:

1. Establishes minimum guidelines for required training.
2. Ensures appropriate training for the Chair and committee members.
3. Provides materials/resources for PI and/or designee to meet training requirements.
4. Notifies Institutional Biosafety Officers (BSOs) about new regulations or modifications related to training, changes in COMS processes/policies.
5. Provides training upon request to IACUC/IRB/Grants management personnel on COMS procedures.

C. Institutional BSO Responsibilities:

1. Delivers and documents biosafety training through methods determined by the institution.
2. Distributes or makes available training resources/references such as Biosafety Manual, Lab Inspection Checklist, autoclave validation process and Lab Emergency Guide.
3. Provides in-person training upon request to laboratories to enable them to perform laboratory and protocol-specific biosafety training.

V. Policy Authority:

The Committee on Microbiological Safety shall enforce this policy.

VI. Related Policies & Regulations

- [COMS Policy Introduction](#)
- [BL2+ Policy](#)

VII. Related References:

- [NIH Guidelines](#)
- [Harvard Environmental Health & Safety](#)
- [eCOMS PI Quick Reference Guide](#)