

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 a COMS protocol-registered research must meet all regulatory and, institutionally mandated training requirements pertaining to CRM
- B. All PIs registered with COMS must complete NIH) Guidelines training prior to initiation of recombinant and synthetic nucleic acids work and not less frequently than once every three years thereafter when research under the Guidelines 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 every three years.
- D. All laboratory staff working on a COMS protocol -registered research must be listed as personnel on a COMS registration and complete general biosafety training and agent-specific biosafety training. 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. Definitions

A. Institutional

IV. Record Keeping Requirement:

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

V. Implementation procedures

A. Monitoring Compliance and Sanctions for Non-compliance:

1. Each institution shall verify PI NIH Guidelines training at the time of COMS protocol submission and laboratory inspection.
2. At the time of COMS registration amendment, renewal, or submission, the PI or their designee will verify the PI and study staff listed on the registration have taken the required biosafety training.
3. Untrained individuals will be prohibited from working on registered COMS research protocols.
4. COMS registration will be suspended if any training non-compliance is not corrected within the allotted timeframe.

B. COMS Responsibilities:

1. Establishes minimum guidelines for required training.
2. Ensures appropriate training for the Committee Chair and members.
3. Provides materials/resources for PI and/or designee to meet training requirements.
4. Notifies Institutional Biosafety Officers (BSOs) about new regulations related to training, changes in COMS processes/policies, training modifications.
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, laboratory emergency response spill kit training guide, etc.
3. Provides in-person training upon request to laboratories to enable them to perform laboratory and protocol-specific biosafety training.

VI. Policy Authority:

The Committee on Microbiological Safety shall enforce this policy.

VII. Related Policies

VIII. References