

Title: Institutional Biosafety Program Policy on Mandatory Training

Effective Date: 09-October-2018

Authorized by: Institutional Biosafety Committee, Office of Laboratory and Field Safety, Office of Research Compliance

Revision History: 03-March-2018, 09-October-2018, 19-August, 2019 (JC)

I. Background

The Central Michigan University Biosafety Program Policy (Policy 3-47) charges the Vice President for Research and the Institutional Biosafety Committee (IBC) with ensuring compliance with applicable federal and state laws and regulations, including the National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), The Federal Select Agent Program (7 C.F.R. Part 331, 9 C.F.R. Part 21 and 42 C.F.R. part 73) and The United States Government Policy for Oversight of Dual Use Research of Concern (DURC) and consistent with the guidance found in the Centers for Disease Control's Biosafety in Microbiological and Biomedical Laboratories (BMBL).

II. Purpose

NIH Guidelines section IV-B-1-h defines the following responsibilities of the Institution with regard to ensuring appropriate training for individuals involved in the oversight or conduct of covered research: "Ensure appropriate training for the Institutional Biosafety Committee Chair and members, Biological Safety Officer and other containment experts (when applicable), Principal Investigators, and laboratory staff regarding laboratory safety and implementation of the *NIH Guidelines*. The Institutional Biosafety Committee Chair is responsible for ensuring that Institutional Biosafety Committee members are appropriately trained. The Principal Investigator is responsible for ensuring that laboratory staff are appropriately trained. The institution is responsible for ensuring that the Principal Investigator has sufficient training; however, this responsibility may be delegated to the Institutional Biosafety Committee." The purpose of this policy is to define how the Institution will meet the outlined responsibility for ensuring appropriate training.

III. Definitions

Institution: The designated entity listed on the IBC registration with the National Institutes of Health Office of Science Policy. For the purposes of this policy, the Institution is Central Michigan University.

Principal Investigator (PI): The faculty or staff member listed on the CMU Biosafety Registration Form as the individual responsible for overseeing the conduct of the research described in the registration, including supervision of research personnel.

Researcher(s), Research Personnel, Research Staff or Laboratory Personnel: Any person (agent), including faculty, staff, contract employees, students and volunteers conducting non-exempt biohazardous research under the supervision of a PI. Any person conducting research under the auspices of CMU and/or the CMU IBC is considered an "agent" of CMU.

IV. Policy

It is the policy of Central Michigan University (CMU) and the CMU IBC that all individuals involved in oversight of potentially biohazardous research (IBC committee members) will be provided training to ensure their understanding of the NIH Guidelines and other relevant laws and regulations as described in section I above. It is the policy of the CMU IBC that documentation of this training will be maintained.

It is the policy of Central Michigan University (CMU) and the CMU IBC that all individuals involved the conduct of non-exempt biohazardous research are required to complete all training outlined in this policy and any additional training required by the IBC, Biosafety Officer or Office of Laboratory and Field Safety prior to participating in the conduct of research. It is the policy of the CMU IBC that documentation of this training will be maintained.

V. Procedures

A. IBC Committee Members:

1. IBC Committee Members will be directed to The Collaborative Institutional Training Initiative ([CITI Program](#)) "Institutional Biosafety Committee Member Training" Course.
2. Community (non-affiliated) members will be asked to review the course materials and will receive guidance and training from the Office of Research Compliance as needed.
3. For all other IBC members this course must be completed during the first six months following appointment to the IBC.
4. Refresher training must be completed at least once every three years.
5. Supplemental training for IBC members will be provided in the form of
 - i. Training materials posted to an IBC shared access account,
 - ii. Training presentations provided by ORC or OLFS staff during convened meetings
 - iii. One on one sessions with ORC or OLFS staff
 - iv. Documentation of supplemental committee member training will be maintained in the form of IBC agendas and minutes describing the supplemental training provided.

B. PIs and Research Staff:

1. All PIs and Research staff listed on IBC protocols, regardless of risk group of the organism or the containment level required will, at a minimum, complete all required Laboratory Safety training prior to initiation of work on an IBC project. Minimum training will include Biosafety Awareness Training, (all BSL2 + BSL3 users) Lab Safety Training (All users) and may include other OLFS training depending upon the nature of the project (e.g. Bloodborne Pathogens Training).
2. All PIs and Research staff working with risk group 2 or higher organisms **will** be directed to [The CITI Program](#) "Basic Biosafety Training" Course.
3. This course must be completed prior to initiation of research activities.
4. The "Biosafety retraining" refresher course must be completed at least once every three years.
5. Supplemental training for Researchers will be provided in the form of:
 - i. OLFS coordinated training which will include: Laboratory and chemical safety, Blood borne pathogen/universal precautions and hazardous waste handling
 - ii. Laboratory specific training provided by the PI and/or Biosafety Officer will include: Appropriate selection and use of Personal Protective Equipment (PPE), proper use of a biosafety cabinet or other specialized equipment, location and use of laboratory safety equipment, procedures for handling spills or emergencies.
 - iii. One on one sessions with ORC or OLFS staff, as needed for specialized research
 - iv. Documentation of supplemental (laboratory specific) training for research personnel will be maintained via the "Biosafety Laboratory Personnel Training Forms".

- a. A copy of this form must be approved or signed, electronically or otherwise, by the researcher, the PI for the project and the Biosafety Officer and will be maintained in the laboratory.
 - b. A copy may also be maintained electronically by the IBC.
6. In addition to the requirements outlined above, personnel requesting access to the BSL3 facility must Complete steps i-iii below and receive formal approval from the IBC prior to being granted access.
 - i. Review laboratory Manual and SOPs with the PI and acknowledge review and understanding of the SOPs by signature.
 - ii. Complete any additional training required by the IBC, OLFS or the BSO following review of the IBC registration and personnel training form.
 - iii. Successfully complete background checks conducted by HR (criminal history) and ORC (export controls and grant/funding agency compliance)

Additional Information:

For questions, additional details or to request changes to this policy, please contact the IBC IBC@cmich.edu or Office of Research Compliance RESCOMPLIANCE@cmich.edu