CMU CENTRAL MICHIGAN UNIVERSITY | Office of Research Compliance

Institutional Biosafety Committee
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Title: Institutional Biosafety Program Policy on Noncompliance
Effective Date: October 9. 2018
Authorized by: Institutional Biosafety Committee, Office of Laboratory and Field Safety, Office of Research Compliance
Revision History: 09/30/16, 01/11/17, 03/06/18, 10/09/18 (JC)

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1. Purpose:
The Institutional Biosafety Committee (IBC) has developed this policy for evaluating issues of non-compliance with IBC protocols, policies and regulatory guidelines. Although uniform standards can serve as a guide, each individual case is unique and will be judged on its own merits.

2. Reporting:
All personnel involved in research overseen by the IBC at Central Michigan University have an obligation to report concerns of noncompliance to the IBC. Any person may report concerns anonymously to the IBC or Office of Research Compliance at:
Report a Research Concern.

3. Applicability:
All IBC approved protocols are conducted in accordance with 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).

4. Authority:
The IBC is charged with ensuring adherence with 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).
As a result, the IBC monitors the conduct of research programs that fall under purview of the CMU Institutional Biosafety Program Policy for compliance with all the appropriate regulations and institutional policies and procedures.

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5. Definitions:

Allegation of Noncompliance: An unproven assertion of noncompliance.

Finding of Noncompliance: A determination by the IBC that an assertion or allegation of noncompliance has been proven or substantiated. Findings of noncompliance by the IBC may include: Violation of University policy or noncompliance with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*, the Biosafety in Microbiological and Biomedical Laboratories (BMBL), OSHA Bloodborne Pathogen Standards, Medical Waste Management Standards, and other applicable federal, state and local laws or regulations governing use of biohazardous materials and/or recombinant or synthetic nucleic acid molecules.

Serious noncompliance means noncompliance that adversely affects the health or welfare of research subjects and/or staff and:

- harms or poses an increased risk of substantive harm to a research subject or staff member; or
- poses a risk of substantive harm to the general public or environment; or
- compromises the integrity or validity of the research;

Continuing noncompliance means noncompliant activity that:

- Recurs after a report of the activity has been evaluated by the IBC and corrective action has been mandated; and may be either minor or serious.
- Note: All continuing non-compliance that recurs after IBC corrective action has been implemented is reportable to the IO and federal agencies as appropriate.

Minor Noncompliance:
Defined as any behavior, action or omission in the conduct or oversight of research activities that deviates from the IBC approved research plan, federal regulations or institutional policies but, because of its nature, does not or did not:

- harm or pose an increased risk of substantive harm to research subjects or research staff; or
- result in a detrimental change to a research subjects clinical status or psychological well-being; or
- harm or pose risk of harm to the general public or environment; or
- have a substantive effect on the value of the data collected.

Examples of minor noncompliance may include, but are not limited to, the following**:**

- Changing study personnel without notifying the IBC;
- Implementing minor wording or procedural changes in a study without first obtaining IBC approval.

Examples of serious IBC Noncompliance may include, but are not limited to, the following:

- Failure of the Principal Investigator (PI) to adhere to the responsibilities outlined in Section IV-B-7 of the *NIH Guidelines*
- Conducting procedures involving biohazardous materials and/or non-exempt recombinant/synthetic nucleic acid molecules without IBC approval
- Working with an infectious agent, viral vector, or host system that is not documented in an approved IBC protocol
- Deviating from approved SOPs in a way that could increase the exposure risk of employees or the environment to biohazardous materials and/or non-exempt recombinant/synthetic nucleic acid molecules
- Conduct of procedures by personnel not adequately trained and with a signed/approved personnel training form on in the lab or on file with the IBC.
- Improper disposal of medical waste
- Conducting procedures involving biohazardous materials and/or recombinant/synthetic nucleic acid molecules in a facility not approved for such use

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- Failure to provide appropriate personal protective equipment (PPE) to personnel who are at risk of exposure to biohazardous materials and/or recombinant/synthetic nucleic acid molecules
- Failure to report an overt exposure to biohazardous materials and/or recombinant/synthetic nucleic acid molecules within the specified reporting timeframe (refer to IBC Policy on Reporting Incidents Involving Biohazard Materials)

6. Investigation and Remediation:

Initial Evaluation and Actions

Upon receipt of a reported concern, the IBC Chair, in consultation with the Office of Research Compliance, the Office of Laboratory and Field Safety and Biosafety Officer when applicable, shall take immediate steps to ameliorate the problem and protect employees. Such ameliorative steps may range from confiscation/destruction of biohazardous materials and/or non-exempt recombinant/synthetic nucleic acids to taking no action other than initiating an investigation into the concern. In some cases, involvement by the Institutional Official (IO), legal counsel, and other University officials (e.g., Department Chair) may be required at the outset of the investigation.

In every investigation, the person(s) against whom the complaint has been raised shall be given notice of the concern and is provided an opportunity to address the allegations in writing.

Following the initial investigation, the IBC Chair shall elect to:

- immediately bring the matter before the Committee; OR
- appoint a Sub-Committee to investigate the allegation; or
- in the instance of minor non-compliance may handle the matter or delegate handling of the matter to the Office of Research Compliance or Biosafety Officer.

As much information as is reasonably needed will be collected during the investigation, which may entail reviewing documents, inspecting facilities, and/or holding discussions with pertinent individuals.

IBC Determination

If the allegations prove legitimate, results of the initial evaluation, including all supporting documentation and the PI's corrective action plan, if developed, will be provided to the Committee for consideration at a convened meeting. Based on the information, the IBC will determine:

1. the nature of the concern as it relates to the *NIH Guidelines*, BMBL, University policy and other applicable regulations;
2. the need for additional actions, such as further investigation or notification of other University officials as appropriate; and
3. further corrective measures to address the concern and prevent recurrence along with appropriate deadlines for response from the PI.

In all cases, the person(s) against whom the allegations have been directed will be notified of the IBC's decisions in writing.

Institutional Responses

The IBC has the authority to address noncompliance with the *NIH Guidelines*, the BMBL, University policies and other regulatory requirements. Findings of noncompliance may result in one or more of the following actions:

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- Suspending the use of recombinant/synthetic nucleic acid molecules and/or biohazardous materials pending completion and acceptance by the IBC of a written plan by the PI for the correction and/or prevention of recurrence.
- Termination of approval for use of recombinant/synthetic nucleic acid molecules and/or biohazardous materials.
- Confiscation and destruction of the recombinant/synthetic nucleic acid molecules and/or biohazardous materials.
- Any other action necessary to protect employees, the environment, the public and/or University, including restricting access to the laboratory in order to suspend activities.

If the identity of the complainant is known, he/she will be notified in writing of the completion of the investigation, with an assurance that appropriate remedial action has been taken as applicable.

Reporting to External Agencies

Findings of serious or continuing non-compliance will be reported to the appropriate agency, including, but not limited to, the NIH Office of Biotechnology Activities, MIOSHA, Department of Public Health, and the Centers for Disease Control and Prevention. The Office of Research Administration – IBC is responsible for reporting any significant problems (e.g. serious non-compliance) with or violations of the *NIH Guidelines* and any significant research-related accidents or illnesses to the NIH/OBA within 30 days of the incident. These reports are not intended to be punitive toward the individuals involved, but rather are intended to assist the institution in developing new and better policies and practices to prevent future non-compliances from occurring.

Confidentiality

Details pertaining to an investigation in progress remain confidential to the extent possible to protect all concerned; however, when the IBC releases the final report of its findings to federal regulatory agencies, those reports may become accessible to the public under the Freedom of Information Act.

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