Carnegie Mellon University Environmental Health & Safety FIRE | LAB | WORK	**Environmental Health and Safety** Institutional Biosafety Committee (IBC) Policies and Procedures
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1. Introduction

CMU is actively committed to preserving the health and safety of its students, staff, and faculty, and to protecting the environment and the community. It is recognized that the use of potentially pathogenic microorganisms and organisms containing recombinant and/or synthetic nucleic acid molecules is necessary in many CMU research and teaching laboratories. To ensure the safe handling of these organisms, Carnegie Mellon University (CMU) requires that all research involving recombinant or synthetic nucleic acid molecules be conducted in accordance with federal and state law, including but not limited to the "Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules" established by the National Institutes of Health.

2. Purpose and Scope

The purpose of this document is to provide information regarding the policies and procedures of the CMU IBC to students, faculty, staff, members of the public, and any other interested parties.

3. Establishment of an IBC

An Institutional Biosafety Committee (IBC) shall be established whose members shall be appointed by the Associate Provost for Research and Academic Administration. The IBC shall consist of at least five members with at least two members coming from the community external to the University and at least one member with experience with research involving animals.

4. Responsibilities of the BSO

The Environmental Health and Safety Office shall appoint a Biological Safety Officer (BSO) who shall also serve as a voting member of the IBC. The BSO duties include, but are not limited to:

a. Periodically performing safety inspections of all laboratories involved with biological research that requires Biosafety Level 2 (BSL-2) containment or higher;
b. Reporting to the IBC any significant problems, violations of the NIH Guidelines, and any significant research-related accidents or illnesses of which the BSO becomes aware unless a report has already been filed by the Principal Investigator;
c. Contribution, development, and updating plans for:
    i. Emergency handling, accidental spills and personnel contamination,
    ii. Exposure Control Plan,
    iii. Biological safety, and
    iv. Occupational Safety and Health Plans;
d. Investigation of laboratory accidents involving recombinant or synthetic nucleic acid molecules;

e. Provision of advice and training on the control and containment of biohazards and security of biological agents;
f. Provision of technical advice and training to Principal Investigators and the IBC on research safety procedures; and
g. Reviews and approves Material Transfer Agreements (MTA), Statements of Work (SOW), and other applicable items that are subject to or potentially subject to the "NIH Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules.

5. Responsibilities of the IBC

The IBC shall be responsible for ensuring CMU compliance with applicable guidelines and federal and state laws. In addition, the IBC shall monitor and review all CMU research involving recombinant and/or synthetic nucleic acid molecules.

6. Authorities of the IBC

The authorities of the IBC include, but are not limited to:

a. Inspection of research facilities;
b. Approval of research involving recombinant and/or synthetic nucleic acid molecules;
b. Obtaining information relating to laboratory practices and procedures, and take such actions necessary to ensure compliance with the applicable guidelines and federal and state laws;
c. Establishment of requirements and guidelines related to the use of biological materials including recombinant and/or synthetic nucleic acid molecules; and
d. Suspension or termination of research in violation of policy or procedure which may create a safety hazard.

7. Responsibilities of the Vice President of Research

The Vice President of Research has assigned the department of Environmental Health and Safety (EHS), specifically the Biological Safety Officer, the responsibility of implementing, establishing and providing oversight of the IBC Policies and Procedures.

8. Responsibilities of the Principal Investigator (PI)

The PI is directly and primarily responsible for the safe operation of the laboratory. His/her knowledge and judgment are critical in assessing risks and appropriately applying the recommendations of the IBC. However, safety is a shared responsibility among all of the laboratory staff. Many resources exist to assist the PI with these responsibilities, including the IBC and the Environmental Health and Safety (EHS) Office. PI shall:

a. Be adequately trained in good microbiological technique;
b. Provide laboratory research staff, students and any other personnel with protocols describing potential biohazards and necessary precautions;
c. Instruct and train laboratory staff, students and any other personnel in the practices and techniques required to ensure safety;

d. Instruct and train laboratory staff, students and any other personnel in the procedures for dealing with accidents;
e. Inform the laboratory staff, students and any other personnel of the reasons and provisions for any precautionary medical practices advised or requested;
f. Supervise laboratory staff, students and any other personnel to ensure that the required safety practices and techniques are employed;
g. Correct work errors and conditions that may result in the release of recombinant or synthetic nucleic acid materials;
h. Ensure the integrity of physical containment and biological containment;
i. Comply with all applicable state and federal regulations and guidelines;
j. Report to the Biological Safety Officer any significant problems, violations of the NIH Guidelines;
k. Report immediately to the Biological Safety Officer incidents including research-related spills and accidents in BSL-2 laboratories resulting in an overt exposure as well as inadvertent release or improper disposal of recombinant or synthetic nucleic acid materials; and
l. Register experiments that involve recombinant and/or synthetic nucleic acid molecules with the IBC.

9. IBC Membership

The committee shall consist of individuals who by their knowledge and experience are qualified to make judgments and recommend policy in the area of recombinant and/or synthetic nucleic acid molecules. Committee membership shall include a representative from each department that is registered with the IBC and/or an individual from each department whose training and experience provides them with knowledge and insight necessary to support the goals of the committee, the Biological Safety Officer and a representative of executive management. Additional members may be included as deemed appropriate or as required by the IBC. The chairperson and vice-chairperson are selected from among the membership. IBC members will be appointed for a period of two years with the option of reappointment.

10. Research that Must be Registered with the IBC

The CMU policy regarding recombinant or synthetic nucleic acid molecules activities requires that all recombinant or synthetic nucleic acid molecules work conducted must be registered with the IBC:

a. All teaching and research protocols using:
    i. Molecules that:
        1. Are constructed by joining nucleic acid molecules, and
        2. That can replicate in a living cell, i.e., recombinant nucleic acids
    ii. 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
    iii. Molecules that result from the replication of those described in (i) or (ii) above must be registered with and reviewed by the IBC.

b. Work involving animals must be submitted to the IBC and to the Institutional Animal Care and Use Committee. Approvals from both committees must be obtained before any work on the protocol can begin.
c. Any change or modification to a currently approved or registered IBC protocol must be approved by the IBC.
d. At this time, CMU does not permit Section III-A, III-B or III-C experiments as defined by the "Guidelines for Research Involving Recombinant and Synthetic Nucleic Acid Molecules."

11. The Charges of the IBC

a. Reviewing ALL research proposals involving recombinant or synthetic nucleic acids
b. Notifying Principal Investigator of review status and committee recommendation
c. Lowering BSL for certain experiments
d. Setting BSL
e. Conducting periodic review to ensure compliance
f. Prescribing emergency plans covering accidental spills and personnel contamination by recombinant agents, as developed and recommended by the Biosafety Officer.
    i. Reporting significant problems or violations of the NIH Guidelines
    ii. Performing other functions as deemed necessary by the institution.

12. The IBC Review Process

a. Protocols are submitted to the BSO where they are initially screened to ensure that applications are complete.
b. Complete protocols are distributed to the IBC by the BSO and recommendations and/or concerns are solicited by each committee member. **NOTE: Exempt protocols can be approved by the BSO prior to submission to the IBC.**
c. Any concern or recommendation is relayed to the investigator by the BSO and the review of the protocol does not resume until concerns or recommendations have been addressed.
d. All fully reviewed applications are placed on the agenda for the next scheduled meeting of the board.
e. Applications on the agenda are reviewed at a convened meeting of a quorum (>50% of voting member attendance) and the committee takes one of the following possible actions:
    i. Full Approval;
    ii. Approval pending IBC Directed Changes; and
    iii. Disapproval.
f. The investigator is notified of the outcome of the committee's review by the BSO.
g. Any application that has been given approval pending IBC directed changes must be revised and resubmitted according to the changes prescribed. This process will be monitored by the BSO.
h. Any application that did not receive approval must fulfill the requirements set forth by the IBC and resubmit accordingly.

13. Conflicts of Interest

IBC Members with a potential conflict of interest during the review and approval of research applications will be required to remove themselves from the meeting and abstain from voting. This action must be noted in the IBC Meeting Minutes.

14. IBC Meeting Minutes

Minutes of each IBC Meeting will be recorded and will contain at a minimum the following information:

a. Section(s) of the *NIH Guidelines* under which the research falls
b. Containment level at which the protocol was approved
c. Animal species used in the protocol if applicable.

Minutes will be made available to the public upon request as outlined in the document, Carnegie Mellon University's Policy on the Public's Request for Minutes and Comments Regarding the Institutional Biosafety Committee.

15. Revisions

Date	Documented Changes	Initials
2/18/2021	Updated Format and Accessibility Update	MAS
3/8/2024	Reviewed and no updates necessary	AL
11/20/2024	Changes to sections 4, 6, 7 and 9	AL