Boston University

Institutional Biosafety Committee Noncompliance Policy

1. Purpose

The Boston University (BU) Institutional Biosafety Committee (IBC) has developed this policy for evaluating issues of noncompliance with IBC protocols, policies, and regulatory guidelines. Although uniform standards can serve as a guide, each individual situation is unique and will be judged on its own merits.

2. Reporting

All personnel involved in research overseen by the BU IBC have an obligation to report concerns of noncompliance to the IBC, Research Compliance, or via the processes outlined for reporting concerns to the University, including the BU Ethics and Compliance Hotline.

3. Applicability

The policy applies to all laboratories conducting IBC-approved activities and the personnel listed on BU IBC-approved protocols.

4. Authority

The BU IBC is charged with ensuring adherence with the National Institutes of Health Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), OSHA Bloodborne Pathogen Standard (29 C.F.R. part 1910.1030), the Federal Select Agent Program (7 C.F.R. Part 331, 9 C.F.R. Part 21 and 42 C.F.R. part 73), The United States Government Policy for Oversight of Dual Use Research of Concern (DURC) and consistency with the guidance found in the Centers for Disease Control's (CDC) Biosafety in Microbiological and Biomedical Laboratories 6th Edition (BMBL). The IBC, therefore, monitors the conduct of research programs that fall under purview of BU for compliance with all the appropriate regulations, as well as institutional policies and procedures. Noncompliance may also be reported to the IBC as a result of annual/routine lab inspections performed by staff of the Environmental Health and Safety (EHS) program.

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: violations of University policy, noncompliance with the NIH Guidelines, the BMBL, OSHA Bloodborne Pathogen Standards, and other applicable federal, state and local laws or regulations governing the 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 (human and animal) and/or staff and:

- Harms or poses an increased risk of substantive harm to personnel; or
- Poses a risk of substantive harm to the general public or environment; or
- Compromises the integrity or validity of the research.

Examples of serious 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;

- Continuing to conduct procedures involving biohazardous materials and/or non-exempt recombinant/synthetic nucleic acid molecules after an IBC protocol has expired;
- Working with an infectious agent, viral vector, or host system that is not documented in an approved IBC protocol;
- Deviating from approved IBC protocol in a way that could increase the exposure risk of personnel or the environment to biohazardous materials and/or non-exempt recombinant/synthetic nucleic acid molecules;
- Conducting of procedures by personnel not adequately trained but with a signed/approved personnel training form in the lab or on file with the IBC;
- Conducting procedures involving biohazardous materials and/or recombinant/synthetic nucleic acid molecules in a facility not approved for such use.

Continuing noncompliance means noncompliant activity that recurs after a report of the activity has been evaluated by the IBC (which may be either minor or serious) and after corrective action has been communicated in writing (e.g., email) to the PI. Note: determinations of continuing non-compliance that recur after IBC corrective action has been implemented may be reportable to external oversight authorities, as appropriate.

Minor noncompliance means any behavior, action, or omission in the conduct or oversight of research activities that deviates from the IBC-approved research plan, federal regulations, local, or institutional policies, but does not rise to the level of serious noncompliance.

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

- Failure to respond to requests for revisions to protocols by the IBC in a timely manner;
- Addition of study personnel without notifying the IBC;
- Implementing minor wording or procedural changes in a study without first obtaining IBC approval.

6. Determinations and Corrective Actions

Initial Evaluation and Actions

A concern may be reported through various channels. Depending on the channel, and the nature of the concern, other offices and individuals will be informed, and in consultation with Research Compliance staff, the IBC Chair, EHS, and the Biosafety Officer, when applicable, immediate actions may be taken to address the concern. The PI will be notified in writing of these concerns and any required actions. During an evaluation it may be necessary to review research and other documentation, inspect facilities, and/or hold discussions with pertinent individuals including the PI, lab personnel and/or administrative personnel, as appropriate. In some cases, involvement by the Institutional Official (IO), BU Office of General Counsel (OGC), and other University administration (e.g., Department Chair) may be required at the outset of an evaluation.

IBC Determination

Following an evaluation, the IBC Chair, in consultation with the above parties, may:

- bring the matter before the full IBC;
- appoint a subcommittee to review the reported concern;
- in the instance of minor non-compliance, may handle the matter or delegate handling of the matter to Research Compliance staff or the Biosafety Officer.

Determinations of Serious or Continuing Non-Compliance

If the IBC chair believes that the allegations may be serious or continuing non-compliance, the results of the evaluation, including all supporting documentation and the PI's corrective action plan, if developed, will be provided to the IBC for review 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 policies, 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.

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

- 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 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 personnel, the environment, the public and/or University, including restricting access to the laboratory in order to suspend activities.

The PI will be notified of the IBC's decision in writing. If the allegation involves other BU personnel for whom corrective actions may result, those individuals will be included in any appropriate communications.

Reporting to External Agencies

Findings of serious or continuing noncompliance will be reported to the appropriate agency, including, but not limited to, the study sponsor, NIH Office of Biotechnology Activities (NIH/OBA), the BPHC and the CDC. The IBC, in concert with Research Compliance, 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 thirty (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.

References:

- Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th Edition
- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
- Occupational Safety and Health Standards for Bloodborne Pathogens
- Federal Select Agent Program
- United States Government Policy for Oversight of Dual Use Research of Concern (DURC)