

HMS Primary Responsible Office: Office of Biological Safety

Approval Body: Committee on Microbiological Safety (COMS)

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Policy on Minutes of IBC Meeting

Purpose

The purpose of this policy is to describe the process for completing the minutes of convened meetings of the Harvard University Institutional Biosafety Committee (IBC), commonly referred to as COMS (Committee on Microbiological Safety).

Scope

The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) require the maintenance of meeting minutes under the IBC such that adequately document fulfillment of the review and oversight responsibilities described in Section IV-B-2-b of the NIH Guidelines. In addition to the NIH Guidelines, local public health authorities require the maintenance and provision of IBC minutes for biological laboratory permitting. Meeting minutes will be kept in accordance with applicable federal, state, and local requirements and for the duration specified by Harvard's record retention policies.

IBC minutes and documents must be made available to the public on request (Section IV-B-2-a-7). The NIH Office of Science Policy (OSP) has issued updated guidance pertaining to [minutes](#) (3/28/25) requiring public posting of minutes as of June 1, 2025. Where there are discrepancies between Robert's Rules of Order and Newly Revised and Guidance from NIH, NIH Guidance is followed. To ensure consistency, the following is adopted.

Policy

- I. Documentation
 - A. The information in the minutes must document that COMS has fulfilled its obligations for review and oversight of projects as noted in section IV-B-2 of the NIH Guidelines. The Committee's rationale for decisions is clear.
 - B. Details will exceed the standard set in Robert's Rule of Order. The minutes will contain the following information:
 1. Minutes will document the date and place of the meeting, whether minutes of the prior meeting were approved, a list of the IBC members when and why the meeting was open or closed, all major motions, major points of order, whether the motions were approved and the time of adjournment. The structure of the minutes will reflect the agenda.

2. Attendance will include voting committee members and any Principal Investigators that may attend.
 3. Members who recuse themselves from discussion or voting on a review due to a conflict of interest.
 4. Members who leave the meeting for any reason. Quorum must be maintained.
 5. Members who attended the meeting under discussion may offer modifications to minutes before the IBC.
 6. Principal Investigator's Name, COMS Project Number, and Project Title.
 7. Section of the NIH Guidelines pertinent to the research involved in recombinant or synthetic nucleic acid applications.
 8. Containment conditions (biosafety level) to be implemented.
- II. Distribution of Minutes
- A. The COMS Office of Biological Safety staff, distribute draft minutes as part of the COMS agenda for the meeting at which minutes are scheduled to be approved.
 - B. Members may submit corrections to the COMS Office of Biological Safety prior to the meeting as well as during the meeting. The staff may correct administrative errors as appropriate.
 - C. Distribution of approved minutes is through COMS Office of Biological Safety.
 1. Minutes are submitted to regulatory agencies by this office as part of annual reports, as needed.
 2. Other requests for minutes are also processed by this office. Note that the NIH Guidelines require meeting minutes be available to the public upon request.
- III. COMS Provision of Public Comments to the NIH Office of Science Policy
- A. Upon request and as required by federal, state, and local health authorities, the institution shall make available to the public all Institutional Biosafety Committee meeting minutes and any documents submitted to or received from funding agencies which the latter are required to make available to the public.

In accordance with the NIH Guidelines, COMS shall allow for public review of its actions through the provision of meeting minutes to those that have requested such documentation. COMS, in consultation with the appropriate Institutional Biosafety Officer, Office of Academic and Research Integrity, and Office of General Counsel, shall review and respond to all written public comments/inquiries received in response to public review of meeting minutes in a manner that is consistent with any redaction policy noted in these policies and procedures.

- B. If public comments are made on Institutional Biosafety Committee actions, the institution shall forward both the public comments and the Institutional Biosafety Committee's response to the Office of Science Policy, National Institutes of Health, preferably by e-mail to: NIHGuidelines@od.nih.gov; additional contact information is also available here and on the OSP website (www.osp.od.nih.gov). NIH Guidelines require COMS to provide copies of its minutes to any member of the public, respond to public comments/inquiries received, and report such comments/inquiries and COMS'

response to the NIH. In addition, the Guidelines encourage COMS to have its meetings open to the public.

Definitions

Principal Investigator: The Principal Investigator (PI), or also known as a Project Director or Program Director, is one or more individuals designated by the institution to direct the project or program supported by the NIH grant. Having more than one PI does not diminish the responsibility of the individual PI. On behalf of the institution, the PI(s) is responsible for full compliance with the NIH Guidelines in the conduct of recombinant or synthetic nucleic acid research.

COMS Office of Biological Safety: The Office provides the technical and administrative support to the Committee on Microbiological Safety. The Office records and ensures timely review of public comments/inquiries. The Office reports comments/inquiries and COMS response to the NIH OSP and institutions supported by COMS.

Policy Authority

The COMS Office of Biological Safety of the Harvard Medical School is responsible for supporting the Committee on Microbiological Safety. This includes preparation of IBC meeting minutes as well as the associated record keeping.

Related Materials

- Policy on Redacting Minutes of IBC Minutes