

HMS Primary Responsible Office: Office of Biological Safety

Approval Body: Committee on Microbiological Safety (COMS)

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Contact: COMS@hms.harvard.edu

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, commonly referred to as COMS (Committee on Microbiological Safety).

Scope The NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) require that IBC minutes and documents be made available to the public on request (Section IV-B-2-a-7). The NIH Office of Biotechnology Activities has issued two documents pertaining to minutes (Q&A 5/14/04; Guidance Memo 2/23/07). Where there are discrepancies in Robert's Rules of Order Newly Revised and Guidance from NIH, NIH Guidance is followed. In order 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-b 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. Minutes will document the date and place of the meeting, whether minutes of the prior meeting were approved, whether and why the meeting was open or closed, all major motions, whether the motions were approved and the time of adjournment. The structure of the minutes will reflect the agenda.

Specifically:

1. Attendance will include voting members, ex-officio members, ad-hoc reviewers, consultants, Principal Investigators and guests.
2. Members who recuse themselves from discussion or voting on a review due to a conflict of interest.
3. Members who leave the meeting for any reason. Quorum must be maintained.

4. Members who attended the meeting under discussion may offer modifications to minutes before the IBC.
5. Section of the NIH Guidelines pertinent to the research involved in recombinant DNA applications.
6. Technical information related to the proposed project:
 - Host(s) and vector(s) to be used
 - Agent characteristics such as virulence and pathogenicity.
 - Function of the inserted DNA sequence
 - Types of manipulations
 - Containment conditions 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. Those present at the convened meeting may submit corrections to the Office of Biological Safety office prior to the meeting as well as during the meeting. The Office staff may correct administrative errors as appropriate.
- C. Distribution of approved minutes is through Office of Biological Safety.
 1. Minutes are submitted to regulatory agencies by this office and distributed to each institution.
 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 Biotechnology Activities

- A. 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 and Office of General Counsel, shall review and respond to all written public comments/inquires 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. Public comments/inquiries and COMS' response shall be forwarded in writing to the NIH Office of Biotechnology Activities by the Director of COMS in a timely manner at the address below:

National Institutes of Health
6705 Rockledge Drive, Suite 750, MSC 7985
Bethesda, MD 20892-7985 (20817 for non-USPS mail)

- B. 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 DNA research.

COMS Office of Biological Safety: The Office records and ensures timely review of public comments/inquiries. 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