

HMS Primary Responsible Office: Office of Biological Safety

Approval Body: Committee on Microbiological Safety (COMS)

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Policy on Redacting Minutes of IBC Meeting

Purpose

The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) require that IBC minutes and documents be made available to the public on request (Section IV-B-2-a-7). The previous Section (IV-B-a-2-6) acknowledges that the protection of privacy and proprietary interests is sufficient to redact portions of minutes. The NIH Office of Science Policy has issued updated guidance pertaining to minutes (3/28/25) requiring public posting of minutes as of June 1, 2025. Minutes will be available following COMS approval and redaction as outlined herein.

The COMS Office of Biological Safety of the Harvard Medical School is responsible for supporting the Committee on Microbiological Safety (COMS). This includes preparation of IBC meeting minutes as well as the associated record keeping. The purpose of this policy is to describe how to redact the minutes of convened meetings of the Harvard Institutional Biosafety Committee, or COMS, prior to public release and/or requests for information. To ensure redaction is performed consistently, the following procedure is adopted.

Policy

1. Implementation procedures
 - a. Information not redacted:
 - Statement that members recuse themselves from discussion/voting due to a conflict of interest.
 - Basic information related to risk assessment and containment levels required by the NIH Guidelines for proposed research
 - A list of the COMS members in attendance
 - Principal Investigator (PI) name
 - Project Title
 - Agents used in research
 - b. Information not released to the public:
 - Personal telephone numbers, email addresses, and home addresses of COMS members

- Information that is likely to compromise personal, institutional, or national security
- Whether and/or where Select Agent work is ongoing
- Trade secret or other confidential information
- Laboratory and animal facility locations
- Proprietary information received from sponsors of clinical gene transfer studies
- Proprietary information received from investigators with patents pending
- Proprietary information related to personnel matters
- Details of incidents reported (ex: personally identifiable information, experimental details and locations that fulfill any of the criteria listed above)

2. COMS Provision of Public Comments to the NIH Office of Science Policy

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/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.

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 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.

Select Agent: A biological agent or toxin that has the potential to pose a severe threat to public health and safety, animal or plant health, or animal or plant product as defined under the Federal Select Agent Program

Policy Authority

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Related Materials

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