

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 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 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 Biotechnology Activities has issued two documents pertaining to minutes (Q&A 5/14/04; Guidance Memo 2/23/07). In order to ensure redaction is performed consistently, the following procedure is adopted.

The 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. The purpose of this policy is to describe how to redact the minutes of convened meetings of the Harvard University Institutional Biosafety Committee, commonly referred to as COMS (Committee on Microbiological Safety) prior to public release and/or requests for information.

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
 - b. Information not released to the public:
 - Names, home telephone numbers and home addresses of COMS members
 - Information that is likely to compromise institutional or national security
 - Whether and/or where Select Agent work is ongoing.
 - Trade secret or other confidential information
 - Principal investigator and collaborating researcher's names
 - Laboratory and animal facility locations
 - COMS members names
 - Guests names

- Proprietary information received from sponsors of clinical gene transfer studies
 - Proprietary information received from investigators with patents pending
 - Proprietary information related to personnel matters
2. 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/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. 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 below address:

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

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.

Office of Biological Safety: Records and ensures timely review of public comments/inquiries. Reports comments/inquiries and COMS response to the NIH OBA and institutions.

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

Related Materials/ References

- Policy on Minutes of IBC Meeting