
Yale University Institutional Review Boards

100 GD. 12 Preparation and Maintenance of IRB Minutes

Overview

This document provides guidance to the IRB regarding the preparation and maintenance of minutes that serve as the official record of IRB considerations and determinations of protocols reviewed at a meeting of the fully convened IRB, in conformance with 45 CFR 46.115 (a)(2) and 21 CFR 56.1115 (a)(2). Minutes of IRB meetings shall be in sufficient detail to show that a quorum of members was retained throughout the meeting; appropriate alternates voted when necessary; the actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

General Documentation Requirements

The minutes must include:

- The times at which the meeting is called to order and adjourned.
- Name of Chair.
- A list of attendees, including members, alternates, IRB staff, guests and consultants and, if applicable, the name(s) of a member who attended via teleconference (and for which protocols).
- Descriptions of educational activities conducted at the meeting, including reviews of materials distributed with the meeting packet.
- A statement indicating that members were reminded to identify to the Chair any real or apparent conflict of interest concerning any protocol before the Committee. The Chair will require the member to recuse him or herself from the deliberation and vote of the specific protocol. Members may also be recused on their own initiative.
- A statement indicating that the duration of approval and reapproval is for a period of one year unless otherwise voted by the Committee.
- Reports to the Committee, including protocol deviations, adverse events, unanticipated problems involving risks to participants or others, audit reports, details of disciplinary actions, etc. (if applicable)
- Approval of or changes to minutes from previous meetings.
- Comments, if any, on reports of expedited and exempt activities provided with the meeting agenda.

Required Documentation for Each Protocol

Minute entries should capture the content of discussions and include all required findings and requests made of investigators. Documentation for each protocol must include, at a minimum:

- The title of the protocol, the sponsor (if any), the IRB number, the name of the principal investigator, and the name of the primary and secondary reviewer (when applicable)
- A summary of the purpose of the protocol or, for an amendment, a summary of the amendment request
- For reapprovals, the progress of the study as indicated by, for example: the enrollment status, the number of subjects enrolled over the past year, the number of excluded or withdrawn subjects, and whether or not any adverse events have occurred over the past year.
- Actions taken on each protocol, including vote tallies showing votes for and against and abstentions or recusals
- The name of a member that did not participate in the discussion or vote due to late arrival or early departure

- For recusals, a comment indicating that a named member recused due to a personal or financial conflict of interest
- A statement that the protocol satisfies regulatory criteria for IRB approval of research (45 CFR 46.6.111 and 21 CFR 56.111), with exceptions noted as controverted issues
- Summaries of discussions and resolution of controverted issues
- Justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document. The minutes (or correspondence between the IRB and the investigator) will include such information when the investigator has made such an alteration based on site-specific circumstances (e.g., specific procedure added, or not performed, at Yale).
- Risk assessment (and, if applicable, review interval if less than one year, based on level of risk)
- Grounds for disapproving or deferring approval of protocols
- Documentation of service of alternate members

Protocol-Specific Content

Some protocols will also require, as applicable, special considerations in order to meet review criteria for approval. Documentation should reflect specific regulatory findings regarding matters including, but not limited to:

- Acknowledgment and management of conflicts of interest disclosed by study personnel
- Necessity of parental permission in research involving children
- Necessity for permission of one or both parents, in research involving children
- Findings related to the involvement of pregnant women, fetuses or neonates
- Findings related to the involvement of prisoners
- Findings related to the involvement of individuals with impaired consent capacity
- Additional safeguards required for the involvement of other vulnerable subjects
- Significant Risk/Non-Significant Risk determinations for investigational devices
- IND Exemption criteria being met, or the requirement for IND application
- Consultants' statements
- Review frequency if more frequent than annual, and the reason for more frequent review
- Waiver of documentation of informed consent
- Waiver of informed consent
- Waiver of or alteration to HIPAA authorization

Approval and Retention of Minutes

Draft versions of meeting minutes will be prepared by the IRB coordinator staff for review, correction, and acknowledgment by the Chair or Director. Minutes will be distributed to members for their next convened meeting and also made available electronically for members' review. Once voted as approved by the IRB, approval shall be indicated on the minutes, and hard copies shall be retained by the IRB in binders, and available electronically for retention and access. The approved version shall constitute the official record of proceedings. IRB minutes, which are an official record of research review and approval, shall be retained for at least 3 years after completion of the research.

Availability of Minutes for Review

A copy of the IRB-approved minutes for each IRB meeting is made available to the Institutional Official. The IRB minutes, once approved, may not be altered by anyone except by the IRB Chairperson with the concurrence and approval of the convened IRB (e.g., to correct factual or typographical errors).

All approved minutes shall be accessible for inspection and copying by authorized representatives of OHRP, FDA, or other authorized entities at reasonable times and in a reasonable manner.

References

45 CFR 46.115 and 21 CFR 56.115

Protecting Human Research Subjects: Institutional Review Board Guidebook, (“IRB Guidebook”) found at:
http://www.hhs.gov/ohrp/irb/irb_guidebook.htm

<http://www.hhs.gov/ohrp/humansubjects/guidance/irbq107.htm>; **Guidance Relevant to IRB Records and Documentation**

Revision History:

11/19/2009, 4/23/2010, 5/10/2010