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 applicable regulatory requirements and guidelines (e.g., Common Rule (45 CFR 46.115 (a)(2)); Food and Drug Administration (FDA) 21 CFR 56.115 (a)(2) regulations; and ICH GCP R2, section 3.2.2., 3.4).

General Documentation Requirements

The minutes will include:

- Names of the attendees at the meeting including the Chair (or the individual chairing the meeting), primary members, alternate members as well as their capacity (scientist, nonscientist, nonaffiliated, prisoner representative, etc.), guests, and staff;
- Methods of attendance (in person or alternative method e.g. teleconference);
- When applicable, the names of the primary members for whom alternate members are substituting;
- 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;
- A written summary of the discussion of controverted issues and their resolution;
- Comments, if any, regarding reports of expedited and exempt activities provided with the meeting agenda;
- Comments, if any, regarding minutes from previous meetings.
- 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 vote and may require the member to recuse him or herself from the discussion or deliberation of the specific protocol. Members may also be recused on their own initiative;
- When applicable, descriptions of educational activities conducted at the meeting.

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 IRB number, the name of the principal investigator, and the name of the primary reviewer;
- 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 46.111 and 21 CFR 56.111), with exceptions noted as controverted issues and deferral or disapproval;
- Summaries of discussions and resolution of controverted issues;
- Grounds for disapproving or deferring approval of protocols.
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;
- Documentation of assent 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 and investigational device exemptions (IDEs);
- Investigational New Drug (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 Health Insurance Portability and Accountability Act (HIPAA) authorization;
- For review of issues that require prompt reporting to the IRB under 45 CFR 46.103(b)(5) or 21 CFR 56.108(b) (e.g., an unanticipated problem involving risk to human subjects or others), the minutes will summarize the report and will document the IRB’s action, if any, resulting from that review.

Approval and Retention of Minutes

Meeting minutes will be prepared by the Regulatory Analyst staff for review and correction by the Regulatory Chair, and final approval by the acting Chair (chair, vice-chair, or alternate vice-chair chairing the meeting). The approval shall be recorded in IRES IRB. The IRB members will be notified when meeting minutes are available for their review. Any proposed corrections will be discussed at an IRB meeting and approved by the acting Chair.

The approved version of the meeting minutes shall constitute the official record of proceedings. The IRB minutes, once approved, may not be altered by anyone except an IRB Chair or HRPP/IRB staff to correct typographical or administrative errors.

IRB minutes, which are an official record of research review and approval, shall be retained in accordance with applicable regulatory (45 CFR 46.115, 21 CFR 56.115; ICH GCP R2 (section 3.4); 45 CFR 164.530(j)(1)), contractual, and institutional requirements, whichever is longer.

Availability of Minutes for Review

The IRB minutes, once approved, may not be altered by anyone except by an IRB Chair or HRPP/IRB staff to correct minor typographical errors.

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

References

45 CFR 46.115; 21 CFR 56.115.
International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2) (ICH GCP R2), section 3.2.2; 3.4.


Revision History:

11/19/2009, 04/23/2010, 05/10/2010, 01/15/13, 03/03/2017, 12/11/17, 09/01/2020

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<tr>
<th>Revision Date</th>
<th>Description of Change</th>
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<tr>
<td>09/01/2020</td>
<td>Revise the process of approval of meeting minutes</td>
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