

Institutional Review Board (IRB) Policies & Procedures Manual



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Convended IRB Meeting Minutes

Purpose

This policy describes the information documented in the IRB meeting agenda and minutes.

Policy

The convended IRB meetings will be documented as described within this policy as required by the regulations.

Minutes of IRB meetings are the responsibility of the Assistant Director of Clinical Research Compliance. Draft minutes are to be reviewed by the Director of Clinical Research Compliance prior to submission to the IRB. Minutes are to be presented to the convended IRB at the meeting. Final IRB meeting minutes are then available to the Institutional Official.

For further information about the convended IRB operation, see IRB policy: ***Convended IRB: Operational Review Procedures.***

Procedures

Minutes are to reflect the agenda of each meeting and are to record the discussion and action taken on each agenda item.

The minutes are to include the deliberations, actions, and votes on each protocol that is subject to full IRB review. This includes initial, continuing review, amendment/modification, and unanticipated events.

The proceedings are as follows:

1. Quorum and meeting attendance: The Director of Clinical Research Compliance or their designee will assume responsibility to make sure a quorum is always present.
2. Voting: For each protocol, a vote is taken and recorded. The total number of votes is always equal to the total number of members present at the meeting. The vote is recorded as follows, the number of members who:
 - a. Vote **for** the action recommended
 - b. Vote **against** the action recommended
 - c. Wish to **abstain**
 - d. Are **present at the meeting, but who are not present in the room when the vote is called** (and their name documented).
 - e. **Who left the room for reasons of conflict of interest** (and their name documented)?
 - f. **When an alternate member replaces a primary member**

3. Voting **actions** include:
 - a. Approved
 - b. Conditionally Approved
 - c. Deferred for further review by convened IRB
 - d. Disapproved
 - e. No action taken
4. Discussions related to unanticipated events such as serious and unexpected adverse events, deviations, violations, and whether they are determined to be serious or continuing noncompliance.
5. Discussions of any noncompliant incidents and whether they are determined to be serious or continuing noncompliance.
6. Whether any report that was submitted as:
 - a. Serious or unexpected or
 - b. Unanticipated event involving risks to subjects or others were determined to be an unanticipated event involving risks to subjects or others.
7. Discussion of any administrative issues addressed during the meeting.
8. Notation of all concerns raised about a protocol, including resolutions.
9. Summaries of discussions of controverted/controversial issues and resolutions.
- i. Specific reasons for required changes to research, or for its disapproval.
- j. Documentation of specific findings related to:
 - a. Children
 - i. A risk/benefit determination including whether the IRB agrees with the investigator's determination and justification and/or their own determination and rationale
 - ii. A determination as to whether assent is required
 - iii. If the IRB agrees that an investigator does not need parental permission for an individual less than 18, the rationale utilized by the IRB. This would include a statement as to whether the criteria used in subpart D were used to waive parental permission or a determination that for purposes of the study the individual under 18 may be considered an adult by definition in the regulations
 - iv. A determination as to whether permission from one or both parents/ guardians is required
 - b. Prisoners. A determination as to whether the IRB concurs with the investigator's responses and justifications for the seven regulatory additional determinations as specified in IRB policy: **Prisoners** or a summary of their own determinations and findings
 - c. Pregnant women and fetuses. A determination as to whether the IRB concurs with the investigator's responses and justifications for the regulatory determinations as specified in the IRB Policy: **Pregnant Women, Fetuses and Neonates** or a summary of their own determinations and findings. Determinations regarding 112 MGL 12J.

- d. Waivers and alterations of consent. A determination as to whether the IRB concurs with the investigator’s responses and justifications for waivers an alteration of consent and consent documents as specified in the IRB policy: **Informed Consent** or a summary of their own determinations and findings
- k. Determinations of Non-significant Risk device determinations including whether they concur with the sponsor’s determination or a summary of their own determination and justification
- l. Notation of the duration of the approval period granted or whether administrative updates are required (Note the minutes may reflect that unless otherwise noted, approvals for a one-year period in the minutes)
- m. If a waiver or alteration of informed consent or informed consent documentation is requested, a determination as to whether the IRB concurs with the justification as provided by the investigator or a summary of their own determination and justification
- n. The minutes include a list of all new protocols and continuing reviews since the last meeting that underwent expedited review.
- o. Full Committee IRB Reviewer Worksheets will be uploaded in CHERP. The worksheets are used as a tool to guide review and discussion at the Committee meeting. The meeting minutes and Report of Action letters document the final determinations and actions taken by the agenda.

Related Content

IRB Policies

Informed Consent

Convened IRB: Operational Review Procedures

Pregnant Women, Fetuses, and Neonates

Prisoners

Document Attributes

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