

MINUTES OF IRB MEETINGS

The federal policies for the protection of human subjects [45 CFR 46.115 (a)(2)] require that “Minutes of IRB meetings, which shall be in sufficient detail to show attendance at the meetings; 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.” (Office for Human Research Protections)

Good minutes enable a reader who was not present at the meeting to determine exactly how and with what justification the IRB arrived at its decisions. They also provide the IRB itself with sufficient detail to help it reconstruct its discussions at a later date, if necessary. Comprehensive minutes also demonstrate respect for the human research participants. Meeting minutes do not have to contain information provided in protocols the IRB has previously approved. This process assumes that if IRB members do not discuss a particular issue, the IRB deems the issue acceptable.

PROCEDURES

Minutes Preparation

1. The IRB staff member attending the convened IRB meeting drafts detailed notes to document IRB discussions and determinations. Examples of the type of information included in the minutes are as follows:

- The location of the meeting and the time the IRB convened the meeting and adjourned;
- Documentation of attendance to include:
 - Initial and continued presence of a majority of members (i.e., quorum), including at least one non-scientist;
 - Whether an alternate is voting and for whom he/she is voting;
 - When a member leaves the meeting.
- Minutes on the review of each protocol include the following:
 - The names of any IRB member excused from the meeting due to a conflict of interest during the discussion and vote of the study;
 - Separate deliberations for each action taken by the IRB;
 - A summary of the discussion of any controverted issues and their resolutions;
 - The vote on these actions, including the number of voting “for,” “opposed,” or “abstaining”;
 - The IRB’s determination on frequency of continuing review (based on the degree of risk or the risk/benefit ratio);
 - Name of the investigator and others attending the meeting;
 - The basis for requiring changes in the research;
 - The level of risk determined by the IRB (at initial review; on all other reviews, the minutes only list level of risk if it has changed).

2. When the IRB disapproves a protocol, IRB staff document the basis for the disapproval in the minutes and document discussion of the controverted issues.

3. IRB staff write IRB meeting minutes impersonally and do not attribute opinions expressed by IRB members. Typically, the minutes only identify members by name when they recuse themselves from a particular review due to conflict of interest or leave the meeting for any reason.

4. The IRB considers written comments and/or information provided by ad hoc or cultural consultants in the review process. Ad hoc or cultural consultants may provide comments or recommendations in writing to the IRB prior to the meeting or attend the convened meeting to participate in the review. IRB staff maintain documentation of written comments or reports in the protocol file. In cases where the consultant participates in the meeting, the minutes of the meeting document the information provided by the consultant.

Alternates

1. IRB meeting minutes document when an alternate IRB member replaces a voting IRB member and for whom the alternate is substituting.

2. When alternates substitute for a primary member, the alternate member reviews the same material that the primary reviewer reviewed or would have reviewed.

Tele/Videoconference Participation

1. At a meeting in which IRB members participate via tele/videoconference, meeting minutes document that the IRB member:

- Has received all pertinent material prior to the meeting; and
- Can actively and equally participate in the discussion of all protocols.

Distribution of Minutes

1. IRB staff complete a draft of the IRB meeting minutes.

2. IRB staff disseminate the minutes to IRB members via email.

Record Keeping

1. IRB staff maintain copies of all minutes indefinitely.