Guidance on IRB Meeting Minutes

The Federal regulations for the protection of human subjects (45 CFR 46.115(2) and 21 CFR 56.115(2)) require that "Minutes of IRB meetings . . . shall be in sufficient detail to show attendance at the meeting; 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." These requirements are minimal (see references 3, 4, 5, and 6)

However, it cannot be assumed that all regulatory requirements for review of research have taken place at an IRB meeting unless the IRB minutes record that they were considered and discussed. Good minutes should enable a reader who was not present at the meeting to determine exactly how, and with what justification, the IRB arrived at its decisions. Comprehensive minutes demonstrate respect for the human subjects of research. They should also provide the IRB itself with sufficient detail to help it reconstruct its discussions at a later date if necessary, and thus ensure compliance not only the IRB, but investigators and ISU as a whole.

IRB minutes must uniformly document that the IRB considered all the regulatory review requirements. That is, meeting minutes should reflect IRB determinations that

- risks are minimized and reasonable in relation to anticipated benefits,
- the selection of subjects is equitable,
- informed consent is obtained and documented unless a waiver is granted,
- measures to protect the privacy and confidentiality of data are adequate,
- adequate provisions for monitoring data to ensure safety are made,
- appropriate safeguards for vulnerable populations are in place.

The level of risk determined by the IRB for each protocol must also be documented, with study-specific justification for the determination.

If IRB members participate by telephone, minutes must document that each member received all pertinent material prior to the meeting and can equally and actively participate in the discussion.

Where members have a conflict of interest, IRB minutes should document that the person left the room during the deliberation and vote. If the member was asked to provide information to the IRB, minutes should note that the member remained in the room to provide information but was recused prior to the discussion and vote.

IRB minutes are subject to the Freedom of Information Act (FOIA); therefore they should be written impersonally, and opinions expressed by members should not be attributed to them. Members should only be identified by name when they are recused from a particular review or leave the meeting for any reason, or when the committee bases a decision based on a member’s specific expertise (e.g. a physician member indicates that a medical procedure is consistent with standard practices, etc.). Further, minutes must be written professionally, with attention to correct word usage, grammar, punctuation, complete sentences, consistency in headings and titles, etc.
The writer, at his/her discretion, may cut and paste into the meeting minutes template from the protocol or from reviews received from the primary reviewers for the meeting. However, the writer is responsible for ensuring that information copied is grammatically correct, makes sense in the new context, is free of typos, is in the correct tense, etc. Because minutes are subject to FOIA, they reflect upon the professional image or reputation of the writer and ISU.

The following is guidance regarding information to include in IRB minutes for different types of review. Basic meeting information, such as documentation of quorum, presence of members and visitors, application information, recusals, documentation of the approval period, etc., should be included for all meeting minutes, regardless of the type of review.

**New Studies**

**Purpose and Procedures:** A brief description of the purpose and overview of procedures. Specific details about procedures are not necessary, but readers should be able to get a general idea of what participants are being asked to do.

For previously tabled studies, include a summary of committee requests and a description of the investigator’s response.

**Discussion:** A summary of the discussion of issues identified by the committee, particularly controverted issues and their resolution. In general, any discussion with the investigators should be recorded as a summary and not as a transcription of the conversation; in instances where the PI is providing information that must be documented for the review or in compliance cases, more specific statements may be required. If no controverted issues are discussed, a statement to this effect should be included.

**Subject Selection and Recruitment:** A summary of the types of subjects to be included and recruitment plans, justification for the inclusion or exclusion of specific populations, and documentation of the committee’s determination of whether subject selection is equitable and recruitment plans are non-coercive.

**Risks:** A summary of the foreseeable risk(s) and procedures for minimizing risks identified by the investigator, followed by the committee’s assessment of the risk(s) (e.g., whether additional risks exist, etc.). The minutes should document the committee’s determination that risks have been minimized appropriately or specify the additional procedures that the IRB deems appropriate to minimize the risks.

**Level of Risk:** Documentation of the committee’s assessment of the level of risk (minimal, slightly greater than minimal, or greater than minimal) along with a study-specific justification for the determination and a comparison to the subject’s everyday life (e.g., blood draw procedures in the research present no more risk than blood drawn for screening purposes at the doctor’s office; questions asked in a survey are similar to questions one might be asked during an aptitude exam at school).

**Potential Benefits:** A summary of the benefit(s) identified by the investigator, followed by the committee’s assessment of the anticipated benefit(s).

**Risk/Benefit Ratio:** Documentation of the committee’s determination of whether risks are reasonable in relation to the anticipated benefits of the research.

**Data and Safety Monitoring:** Where applicable, include a description of the data and safety monitoring plan proposed by the investigator followed by the committee’s assessment of whether or not the plan is adequate to ensure the safety of participants. Data and safety monitoring is required when analysis of data would help determine if changes in the research protocol may be necessary based on study results. Otherwise, a statement that data and safety monitoring is not required for the study is sufficient.
Confidentiality: A summary of the plans to maintain confidentiality of the data and protect the privacy of participants, followed by the committee’s determination of whether or not these plans are adequate and why the plans are adequate or not.

Informed Consent: A description of the informed consent process, including whether
- documented consent will be obtained;
- all elements of consent are included in the form; (if not, describe those that are missing);
- there are any special provisions for special or vulnerable populations, such as parental consent, consent of a legal guardian, translation of consent materials, the use of a short form, etc.;
- special requirements for studies regulated by the FDA, those involving genetic information, HIPAA authorization, etc., have been met.

The committee’s determination that the informed consent process is appropriate should also be included.

Waivers: A description of the waiver (i.e., waiver of consent, elements of consent, or documentation of consent), including identification of specific elements to be waived. The committee’s determinations of each of the waiver criteria, with study-specific justification must also be included.

Waivers of the requirement for signed authorization under HIPAA would also be discussed here.

Safeguards for Vulnerable Populations: When applicable, a description of safeguards for participants from vulnerable populations, including the committee’s determination of whether safeguards are adequate.

Special Determinations: The committee’s determinations, including study-specific justification, required for research involving minors, prisoners, or pregnant women, fetuses, or neonates.

Information/Revisions Needed to Grant Approval: A description of the information and/or revisions required by the committee, including the basis for each.

Recommendations: Documentation of the committee’s decision to approve, approve with contingencies, table, or disapprove the application, and who has the authority to grant final approval (i.e., the Chair(s), the IRB).

Continuing Review and Modification

Purpose and Procedures: A brief description of the purpose and overview of procedures. Specific details about procedures are not necessary, but readers should be able to get a general idea of what participants are being asked to do.

A brief overview of past IRB review decisions is also helpful, particularly concerning the level of risk, any waivers that were granted, and any specific findings related to vulnerable populations.

For previously tabled studies, include a summary of committee requests and a description of the investigator’s response.

Modifications: A brief description of the modifications proposed by the investigator or any that were identified during continuing review.

Accrual/Withdrawals: A description of the number of participants who enrolled in the study in comparison to the number approved. Any participant withdrawals should be documented here, along with a discussion about whether or not the withdrawals were due to problems with the study.
Unanticipated Problems/Adverse Events or Subject Complaints: A summary of unanticipated problems, adverse events, or complaints from subjects that were reported. If an adverse event was reported to the IRB during the approval period, a summary of the event and findings of the committee should be included. If the PI has indicated that no problems have occurred, this should be stated.

New Information: A summary of any new information that suggests previously unknown or additional risks to participants or that may impact future participants’ willingness to enroll in the study. If the committee determined that no new information is presented that would impact willingness to participate, this should be stated.

Discussion: A summary of the discussion of issues identified by the committee, particularly controverted issues and their resolution. Any discussion with the investigators should be recorded as a summary and not as a transcription of the conversation. If no controverted issues are discussed, a statement to this effect should be included.

Review of Approval Criteria: Minutes should reflect if the IRB determined that risks to participants continue to be minimized and reasonable in relation to benefits, that subject selection continues to be equitable, that privacy and confidentiality protections are still adequate, as are data safety and monitoring plans and safeguards for vulnerable participants, and that the informed consent process continues to be appropriate. A statement such as “the IRB determined that because study procedures have not changed and no problems or adverse events occurred, the study continues to present only minimal risk to participants and may continue as previously approved” is appropriate if no modifications are proposed. If the committee does not make this finding, the reasons why should be stated.

Information/Revisions Needed to Grant Approval: A description of the information and/or revisions required by the committee, including the basis for each.

Recommendations: Documentation of the committee’s decision to approve, approve with contingencies, table, or disapprove the application, and who has the authority to grant final approval (i.e., the Chair(s), the IRB).

Modification

Purpose and Procedures: A brief description of the purpose and overview of procedures. Specific details about procedures are not necessary, but readers should be able to get a general idea of what participants are being asked to do.

A brief overview of past IRB review decisions is also helpful, particularly concerning the level of risk, any waivers that were granted, a history of adverse events, and any specific findings related to vulnerable populations.

For previously tabled studies, include a summary of committee requests and a description of the investigator’s response.

Modifications: A brief description of the modifications proposed by the investigator.

Discussion: A summary of the discussion of issues identified by the committee, particularly controverted issues and their resolution. Any discussion with the investigators should be recorded as a summary and not as a transcription of the conversation. If no controverted issues are discussed, a statement to this effect should be included.

Review of Approval Criteria: Minutes should reflect the IRB determination of whether or not the modification changes the level of risk or any previous determinations related to approval. Study-specific justification should be included when the modification directly affects one or more approval criteria (e.g.,
if a new type of participant is added, justification for why subject selection continues to be equitable should be documented).

Information/Revisions Needed to Grant Approval: A description of the information and/or revisions required by the committee, including the basis for each.

Recommendations: Documentation of the committee’s decision to approve, approve with contingencies, table, or disapprove the application, and who has the authority to grant final approval (i.e., the Chair(s), the IRB).

Adverse Events

Description: A summary of the event, the investigator’s response, and any other pertinent details.

Discussion: A summary of the committee’s discussion of the event.

Determinations: Documentation of the IRB’s determinations of whether or not

- the event is serious or related to the study,
- the study should proceed,
- any information about the event should be shared with current participants,
- the consent form should be revised to inform participants of new risks.

Potential Noncompliance

Description: A summary of the potential noncompliance.

Discussion: A summary of the committee’s discussion surrounding the issue.

Determinations: Documentation of the IRB’s determinations of

- whether or not the situation constitutes noncompliance,
- the level of noncompliance (minor, serious, continuing), including justification (e.g., the reason why the noncompliance was not considered serious),
- corrective actions to be employed.

New Business/Education

The following items should also be documented in the minutes:

- A brief description of the topic of any educational or training information provided during meetings
- A brief description of any policies under review and IRB decisions to adopt or revise policies
- Other miscellaneous discussions as applicable

References