

Tip Sheet 3: Documenting Discussions and Decisions on Research Studies and Activities

Related Accreditation Elements: II.5.B.

The IRB or EC must document discussions, decisions, and findings. This can be accomplished either through the IRB or EC minutes or, in the case when the expedited procedure for review is used, through documentation in the protocol file or other records.

IRB or EC minutes should be clear about the actions of the IRB or EC and exactly what the IRB or EC approved. Minutes should specify the modifications required to secure approval and the reason the IRB or EC is requesting the modifications. Minutes should indicate proposals or motions voted upon by the IRB or EC, and the results of each vote. When conducting initial or continuing review, minutes should document the IRB's or EC's determination of the approval period.

When the convened IRB or EC takes votes, there is no requirement to indicate how individuals voted. However, it should be possible to determine from the minutes the names of the individuals who were present for the vote. Minutes should reflect when an alternate member replaces a primary member and document the name of the primary member replaced. When an IRB or EC member leaves the meeting because of a conflict of interest, minutes should document the name of the absent IRB or EC member along with the fact that a conflict of interest was the reason for the absence.

IRB or EC minutes should summarize the discussion of controverted issues and their resolution. Summary statements can be used to capture the discussion of controverted issues, such as "The IRB or EC discussed the appropriateness of a placebo control given the availability of an active treatment" or "The IRB or EC discussed whether the proposed payments would be an undue influence to children or their parents." Simple statements can also be used to indicate the resolution of issues, such as "The IRB or EC decided that a placebo control was appropriate given the benign nature of the condition under study" or "The IRB or EC decided that a \$10 gift certificate for a toy would be more appropriate as payment as it would not be unduly influential." IRBs or ECs should summarize the discussion of controverted issues even when the resolution of the issue is to accept the protocol as submitted.

When the laws or regulations require the IRB or EC to find and document certain determinations, such as for waivers of the consent process or for research involving children, minutes or the records should document each of the required determinations that the IRB or EC needs to make to approve the research along with protocol-specific findings that justify each of the determinations. For example, the IRB or EC might document one of the four criteria for a waiver

of the consent process as, “The IRB or EC found that: (1) The research involves no more than minimal risk to participants because the risk is limited to a breach of confidentiality and the data will be secured to keep that risk minimal. (2) The waiver or alteration will not adversely affect the rights and welfare because there are no other laws or ethical standards that require consent or forbid disclosure of this information for research purposes. (3) The research could not practicably be carried out without the waiver, because most of the participants cannot be located. If consent were a requirement at least 50% of participant data could not be obtained and the missing participants would most likely represent individuals with more severe disease who had to move out of the area. Since this is an epidemiology study looking at a low probability event, such a loss would lead to invalid results and an inability to conduct the research. (4) Providing participants with additional pertinent information is not appropriate because most of the participants cannot be located and there will be no communication with participants.

IRB or EC minutes should document:

1. Actions taken by the IRB or EC.
2. Separate deliberations for each action.
3. Votes for each protocol as numbers for, against, or abstaining.
4. Attendance at the meeting.
5. When an alternate member replaces a primary member.
6. The basis for requiring changes in research.
7. The basis for disapproving research.
8. A written summary of the discussion of controverted issues and their resolution.
9. The names of IRB or EC members who leave the meeting because of a conflict of interest along with the fact that a conflict of interest is the reason for the absence.
10. For initial and continuing review, the approval period.
11. Required determinations and protocol-specific findings justifying those determinations for:
 - a. Waiver or alteration of the consent process.
 - b. Research involving pregnant women, fetuses, and neonates.
 - c. Research involving prisoners.
 - d. Research involving children.
 - e. The rationale for determining that risk associated with using a medical device in a study significant or non-significant (referred to as significant risk/non-significant risk device determinations).