

DEPARTMENT: INSTITUTIONAL REVIEW BOARD
POLICY NUMBER: 044
SECTION: RECORDS AND DOCUMENTATION
REVIEW RESPONSIBILITY: IRB
EFFECTIVE DATE: AUGUST 13, 2003
REVISION DATE:
LAW IMPLEMENTED: 45 CFR 46.115

SUBJECT: Documentation of IRB Committee Meeting Minutes

1. The minutes of all IRB Committee meetings must be in sufficient detail to show:
 - a) Attendance at the meetings, including whether an alternate is voting, when a member leaves the room, when a member absents themselves during the vote due to a conflicting interest, and the initial and continued presence of a majority of the members, including at least one nonscientist member.
 - b) For each protocol discussed, the actions taken by the IRB Committee, the vote on these actions including the number of members voting for, against, and abstaining, in the following format: Total 14, Vote: for-13, Opposed-0, Abstained-1(Name). This method demonstrates the continued existence of a quorum at the meeting.
 - c) When a protocol is approved, the minutes should reflect that the IRB Committee determined that the risks to subjects are minimized and reasonable in relation to the anticipated benefits, that the selection of subjects is reasonable in relation to anticipated benefits, that informed consent is appropriately documented, and that there are provisions for safety monitoring of the data, protections to ensure the privacy of subjects and confidentiality of data, and appropriate safeguards for vulnerable populations.
 - d) When protocol revisions are requested or a proposal is disapproved, the basis for doing so should be recorded.
 - e) A written summary of the discussion of controversial issues and their resolution.
 - f) Expedited and exempt application review and approvals for the previous month.
 - g) Continuing review determinations.
2. The minutes of the IRB meetings should reflect the Committee's determination regarding which protocols require continuing review more often than annually, as appropriate to the degree of risk, and the approval period if other than annually. Minutes for continuing review should reflect that the Committee determined that the risks to subjects continue to be minimized and reasonable in relation to the anticipated benefits, that the selection of subjects continues to be reasonable in relation to anticipated benefits, and that informed consent continues to be appropriately documented. Also documented should be any provisions for the safety

monitoring of data, protections for privacy of subjects and confidentiality of data, and that appropriate safeguards are in place for vulnerable populations.

3. When specific findings on the part of the IRB are required these finding should be fully documented in the minutes and should include protocol specific information justifying each IRB finding.
 - a) When approving a procedure which alters or waives the requirements of informed consent, the minutes must document the findings as required.
 - b) When approving a procedure which waives the requirement for obtaining a signed consent form, the minutes must document that the Committee made the findings as required.
 - c) When approving research involving prisoners, the minutes must reflect that the Committee made the additional findings which authorizes the research required in the federal regulations. The recordkeeping must reference that either a majority of the IRB Committee has no association with the prison(s) involved, apart from their membership on the IRB, or at least one member of the IRB Committee is a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a research project is reviewed by more than one IRB, only one IRB need satisfy this requirement. Note: if a prisoner representative is selected to serve on the IRB Committee, the person must have a close working knowledge of prison conditions and the life of a prisoner. Suitable individuals include present or former prisoners, prison chaplains, prison psychologists, prison social workers, or other prison service providers, persons who have conducted advocacy for the rights of prisoners, or any individuals who are qualified to represent the rights and welfare of prisoners by virtue of appropriate background and experience.
 - d) When approving research involving children, the minutes must document that the Committee made the findings as required in the federal regulations. Note: When reviewing research involving children who are wards of the state or any other agency, institution, or entity, the IRB must find and document in the minutes that such research is related to their status as wards or conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.
4. Meeting minutes must document when an alternate Committee member replaces the appointed Committee member.
5. At a meeting in which Committee members participate by telephone, meeting minutes must document that each participating IRB Committee member has received all pertinent material prior to the meeting, and can actively and equally participate in the discussion of all protocols.

6. If reviewing protocols that anticipate an emergency situation, the IRB minutes must specifically record the licensed physician member's affirmative vote.
7. Copies of the IRB Committee's minutes should be distributed to the IRB Committee members, and the Associate Vice President of Research. The minutes shall be made available for review by the Vice President for Research.