Procedure

Subject: Procedure for Documentation of IRB Committee Meeting Minutes

Procedure:
This procedure provides guidance on completing documentation of the Institutional Review Board (IRB) Committee meeting minutes.

I. Regulatory Compliance Analyst (RCA) Responsibilities.
A. The RCAs attending the convened IRB Committee meeting will draft notes in detail to document the IRB Committee discussions and determinations. The minutes of all IRB Committee meetings must be in sufficient detail to demonstrate:
   1. Attendance at the meeting, to include:
      a) Whether an alternate is voting and for whom they are voting;
      b) When a member leaves the room;
      c) When a member absents themselves during the vote due to a conflict of interest and
      d) Initial and continued presence of a majority of members, including at least one nonscientist
   2. IRB Committee Member conflicts of interest should be identified at the beginning of the meeting and documented in the appropriate section of the IRB minutes.
   3. For each protocol discussed, the minutes should detail:
      a) The assigned reviewers and their scientific or non-scientific status as indicated on the IRB Committee rosters [e.g. NS (non-scientist), OS (other scientist), PS (physician scientist), SS (social scientist), and/or a non-affiliated member], including the use of any expert consultants and their scientific or non-scientific status and specialty;
      b) If a Committee Member is excused from the meeting due to a conflict of interest during the discussion and vote of the study;
      c) Actions taken by the IRB Committee;
      d) Discussion of any controverted issues and resolutions;
      e) If discussing a suspension or notification of expiration, issues that arise where treatment may be continued for safety purposes;
      f) The vote on these actions including the number of voting “for,” “against,” or “abstaining”; and
      g) In order to document the continued existence of a quorum, votes should be recorded in the minutes using the following format: Total Votes = 15, For: 14, Against: 0, and Abstained: 1 (last name of abstaining member).
   4. When a protocol is approved, the minutes should reflect the criteria for approval found in regulations45 CFR 46.111 and if applicable, 21 CFR 56.111 have been discussed and the rationale documented (See HRPP Policy III.E).
   5. When a protocol is approved, the level of risk (e.g., minimal or greater than minimal) and the approval period (review interval) appropriate to the level of risk should be determined.
   7. When protocol revisions are requested or a proposal is disapproved, the basis for the disapproval should be included as well as discussion of the controverted issues.
B. Continuing Review.

1. The minutes of IRB meetings should clearly reflect the IRB Committee’s determination regarding which protocols require continuing review more often than annually, as appropriate to the risk, and the approval period; and

2. The minutes should reflect the criteria for approval found in regulations 45 CFR 46.111 and if applicable, 21 CFR 56.111 have been discussed and the rationale documented (See HRPP Policy III.K).

3. The minutes should reflect the level of risk (e.g., minimal or greater than minimal) and the approval period, appropriate to the level of risk.

C. NIH-Supported Multi-center Clinical Trials. When the IRB Committee reviews NIH-approved informed consent documents for NIH-supported multi-center clinical trials, the minutes should reflect any instance in which the IRB Committee requested or approved the Investigator’s deletions or substantive modifications of information concerning risks or alternative procedures contained in the NIH-approved sample informed consent document.

D. Specific Findings. When specific findings on the part of the IRB Committee are required, these findings should be fully documented in the IRB Committee minutes and should include protocol specific information justifying each. For example:

1. Alteration or Waiver of Informed Consent. When approving a procedure that alters or waives the requirements of informed consent, the minutes must document that the Committee made the findings in accordance with HRPP policy (See HRPP Policy IV.C).

2. Waiver of Documentation of Informed Consent. When approving a procedure that waives the requirements for obtaining a signed informed consent document, the minutes must document that the Committee made the findings required in accordance with IRB policy (See HRPP Policy IV.B).

3. Research Involving Prisoners. When approving research involving prisoners, the minutes must document that the Committee made the seven additional findings and the specific category, which authorizes the research, required in accordance to HRPP policy (See HRPP Policy IX.B).
   a) Additionally, the minutes must reference that a majority of the IRB Committee (exclusive of prisoner member/representative) has no association with the prison(s) involved, apart from their membership on the IRB; and
   b) 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 where a particular research project is reviewed by more than one IRB, only one IRB need satisfy this requirement.

4. Research Involving Children. When approving research involving children, the minutes must document that the Committee made the findings in accordance with HRPP policy (See HRPP Policy IX.A).

5. Wards of the State or Other Agency. 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
   a) Related to the child’s status as wards; or
   b) Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as participants are not wards.

6. Research Involving Fetuses, Pregnant Women, Neonates or Research on Transplantation of Fetal Tissue. When approving research involving fetus, pregnant women, neonates, or the transplantation of fetal tissue, the minutes must document that the Committee made the findings in accordance with HRPP policy (See HRPP Policy IX.C).

7. Research Involving Cognitively Impaired. When reviewing research involving individuals who are determined to be cognitively impaired and/or...
lack decision capacity, the IRB must find and document in the minutes that the use of a Health Care Decision-Maker/Surrogate is appropriate and that the Health Care Surrogacy rider was reviewed and approved for such use (See HRPP Policy IX.D).

E. Alternates. Meeting minutes must document when an alternate Committee member replaces a voting Committee member and for whom the alternate is substituting. Alternates should have the same scientific or non-scientific status as the Committee Member for whom they are substituting eg. NS, OS, PS, SS.

F. Telephonic Participation. At a meeting in which Committee members participate via telephone, meeting minutes must document that each participating IRB Committee member
1. Has received all pertinent material prior to the meeting and
2. Can actively and equally participate in the discussion of all protocols, in accordance with IRB procedure (See HRPP Procedure III.E.1).

II. Emergency Situations. When reviewing research activities that anticipate an emergency situation the IRB Committee meeting minutes must specifically record the licensed physician member’s affirmative vote (See HRPP Policy IV.C).

A. Distribution of Minutes.
1. The RCA will utilize the database system for completing a draft of the IRB Committee meeting minutes and will forward to all IRB Committee members who were present at the convened meeting. The RCA will instruct the IRB Committee members to review and communicate to the RCA any necessary revisions
2. The RCA will e-mail the final version of the minutes to the Committee members prior to the next convened meeting.
3. The Committee members will call for changes and discuss.
4. Once approved, the minutes are finalized and forwarded to the IRB Committee Chair or designated Committee member for signature. The signed copy is retained in the IRB Committee meeting minutes file, documented in the database and a copy is made available to the Associate Vice Chancellor for Research

III. IRB Committee Responsibilities.

A. The Primary Reviewer is responsible for providing justification for approval under criteria 45 CFR 46.111 and if applicable, 21 CFR 56.111 and for providing documentation of the justification on the “Reviewer’s Comment Form”

B. Each Committee member present during the convened meeting will review the minutes and forward any necessary revisions to the RCA. Once revisions are finalized, the minutes will be forwarded and the final approval vote for acceptance of the minutes will take place at the next convened meeting

C. Copies of each IRB Committee’s minutes should be distributed to the IRB Committee members The approved meeting minutes are automatically distributed to the IRB Medical Director, a representative of the Vanderbilt University Department of Risk Management, and the Associate Vice Chancellor for Research.

D. The approved meeting minutes are made available to the Associate Vice Chancellor for Research and the Vice Provost for Research.

References:
45 CFR 46.108
45 CFR 46.111
45 CFR 46.115(a)(2)
OHRP Compliance Activities: Common Findings and Guidance, July 10, 2002