Department: **UAMS Institutional Review Board**
Policy Number: **6.3**
Section: **Documentation**
Effective Date: **July 31, 2002**
Revision Date: **February 1, 2005; June 1, 2005; January 24, 2011; March 11, 2011; July 21, 2020; August 15, 2022**

SUBJECT: Meeting Minutes

POLICY
Convened IRB committee activities, decisions, and determinations shall be documented in meeting minutes.

PROCEDURE

A. The IRB office staff shall record the meeting minutes.
   1. Material entered directly into the IRB e-system for individual protocols, e.g. via checklists, review notes, or other methods, shall also be considered part of the minutes for studies reviewed by the convened IRB.
   2. Determinations and related information for reviews done using expedited procedures shall be documented in the IRB's e-system.

B. The minutes shall document the following:
   1. Attendance: The minutes of all IRB committee meeting minutes shall be in sufficient detail to show attendance, including the following items:

      a. The names of all regular members in attendance. Regular members' representative capacity is recorded on the IRB rosters.
      b. When there is a consultant or guest attending.
      c. Whether an alternate is voting.
      d. When a member leaves the room.
      e. The continued existence of a quorum.
      f. Initial and continued presence of a majority of members, including at least one nonscientist member.
      g. Presence of non-voting members.

C. Actions: For each item reviewed, the minutes must document the following:
   1. The IRB protocol number, title, and assigned reviewers.
   2. Actions taken and determinations made by the IRB Committee
   3. The vote on these actions including the number of members voting for, against, and abstaining. The abstaining member's name will be noted to document that any member with a conflict abstained.
   4. The name of any member who leaves the meeting due to a conflict of interest.
   5. Discussion and resolution of controverted issues.
   6. Document approval versions.
   7. Revisions required and the basis for any revisions required, or for declining or tabling a study.
   8. Accrual goal, for new protocols only.
   9. For new submissions and continuing reviews, a determination on the length of time between continuing reviews (approval period).
   10. For new protocols, the level of risk assigned to the study.
   11. For Continuing Reviews, whether based on the information presented, there has been any change in the risk.
   12. When a new protocol is approved, the IRB records should reflect that the IRB Committee determined that all approval criteria as outlined in IRB Policy 7.1 were met.
   13. For Continuing Reviews, it should be noted that the study still meets each of the approval criteria or, if information presented impacts any of the approval criteria, changes required in order to grant approval.

D. Specific Findings. When specific findings on the part of the IRB Committee are required, these findings shall be documented in the minutes, including protocol-specific information justifying each IRB finding.
   1. If a waiver or alteration of informed consent was approved, documentation that the requirements as outlined in IRB Policy 15.3 were met.
   2. For device studies, a determination of Significant Risk or Non-Significant Risk and the basis thereof as outlined in IRB Policy 18.2.
   3. In studies to be suspended or terminated, when treatment may continue for safety reasons as outlined in IRB Policy 7.9.
   4. In studies involving prisoners, or those likely to become incarcerated, the seven findings and category of research as outlined by IRB Policy 17.9, as well as the presence of the Prisoner Representative.
   5. In studies involving children or wards, the specific requirements and determinations made as outlined in IRB Policy 17.1.
   6. In studies involving pregnant women, fetuses, or *In Vitro* Fertilization, the specific requirements and determinations as outlined in IRB Policy 17.8.
   7. In studies involving the cognitively impaired, the specific requirements as outlined in IRB Policy 17.2.
   8. For any study in which a DHHS approved sample informed consent document has been provided, any substantive modifications or deletions required.

E. Distribution and Finalization of Minutes: Minutes from the prior meeting of a particular committee are distributed with the next agenda for that committee.
   1. Any corrections/comments to the minutes shall be noted in the minutes of the next meeting.
   2. Once approved by the convened IRB, the minutes may not be modified.
   3. The final minutes shall be retained indefinitely in the IRB e-system and shall be routinely accessible to IRB Reviewers, staff, and compliance personnel. Others may be granted access as needed.
   4. Any requests to access minutes by someone who does not have routine access shall be referred to the IRB chair, director, or associate director.

REFERENCES

45 CFR 46.115(a)(2)
21 CFR 56.115(a)(2)
FDA/OHRP Guidance *Minutes of Institutional Review Board (IRB) Meetings. Guidance for Institutions and IRBs*
AAHRPP Element II.5.B
AAHRPP Tip Sheet 3, *Documenting Discussions and Decisions on Research Studies and Activities*