

SOP: IRB Meeting Minutes

1 PURPOSE

- 1.1 This procedure establishes the process to record minutes for convened meetings.
- 1.2 The process begins when the meeting is called to order.
- 1.3 The process ends when the minutes are approved by the IRB chair or IRB Manager.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None.

3 POLICY

- 3.1 Minutes are to comply with regulatory and guidance requirements.
- 3.2 Minutes are to record separate deliberations for each action.
- 3.3 Minutes are officially approved on behalf of the IRB by the IRB chair or IRB manager.
- 3.4 IRB members may make corrections to minutes.
- 3.5 The IRB writes minutes and makes them available for review by the committee by the next IRB meeting. Minutes are made available to the Institutional Official/ Organizational Official (IO/OO).
- 3.6 Minutes may not be altered by anyone including a higher authority once accepted by the convened IRB.

4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.

5 PROCEDURE

- 5.1 Use the HRP-501 - TEMPLATE MINUTES to record observations at meetings.
- 5.2 Under "Attendance Table" record each voting member (regular members and alternates) present at the meeting at any time. (Do not record non-voting members under "Attendance Table.")
 - 5.2.1 Name.
 - 5.2.2 Status: E.g., chair, vice chair, scientific member, non-scientific member, unaffiliated member, representative of vulnerable population (specify), prisoner representative, alternate member.
 - 5.2.3 For alternate members who are substituting for a regular member, indicate the name of the regular member for whom the alternate member is substituting.
 - 5.2.4 Whether the member was present by teleconference.
- 5.3 Record the total number of members in HRP-601 - DATABASE - IRB Roster. Exclude alternate members in this count.
- 5.4 Record the number of members required for quorum. Divide the number of members by two and select the next whole number. For example, if there are 10 IRB members on the HRP-601 - DATABASE - IRB Roster, then $10/2 = 5$ and the next whole number is 6. If there 11 IRB members on the HRP-601 - DATABASE - IRB Roster, then $11/2=5.5$ and the next whole number is 6.
- 5.5 Indicate whether members present by teleconference received all pertinent material before the meeting and were able to actively and equally participate in all discussions. Delete if no members were present by teleconference.
- 5.6 Record the meeting start time.

- 5.7 Record a summary of each business item that was discussed.
- 5.8 For each protocol reviewed record:
- 5.8.1 Type(s) of review: Initial review, continuing review, review of modifications to previously approved research, or review of Unanticipated Problem Involving Risks to Subjects or Others, Serious Non-Compliance, Continuing Non-Compliance, Suspension of IRB Approval, Termination of IRB Approval.
 - 5.8.2 Protocol Title
 - 5.8.3 Investigator name
 - 5.8.4 IRB identification number
 - 5.8.5 Funding Agency (indicate “none” if none)
 - 5.8.6 Grant Title (indicate “none” if none)
 - 5.8.7 Grant ID (indicate “none” if none)
 - 5.8.8 IND or IDE (indicate “none” if none)
 - 5.8.9 Documents reviewed
 - 5.8.10 Notes: Summarize issues useful to understand the agenda item. For example, a brief history of recent IRB actions
 - 5.8.11 Consultant report: Summarize the key information provided the consultant. Delete if there was no consultant.
 - 5.8.12 Controverted issues and their resolution. Summarize the issues where IRB members expressed a difference of opinion. For each issue indicate the resolution or indicate that there was none. If no controverted issues, indicate “None.”
 - 5.8.13 Motion: Approved, Modifications Required to Secure Approval, Deferred, Disapproved, Suspended, or Terminated. For initial or continuing review add the period of approval to the motion. If the protocol was tabled, indicate this.
 - 5.8.14 Vote: Record as the number of members for, against, abstaining, absent, or recused. List the names of IRB members who were absent or recused. Do not count votes of consultants. If both a regular IRB member and the alternate IRB member are present at the meeting record the vote of just one.
 - 5.8.14.1 For: Voting for the motion.
 - 5.8.14.2 Against: Voting against the motion.
 - 5.8.14.3 Abstain: Present for the vote, but not voting “For” or “Against.”
 - 5.8.14.4 Absent: Listed under “Members Present” but not present for the discussion and vote on this protocol for reasons other than a Conflicting Interest. List the names of absent members in the vote. For example: “For: 7 Against: 3 Abstain: 2 Absent: 2 (Alice Baker, Charlie Delta) Recused: 0 Substitutions: 0.”
 - 5.8.14.5 Recused: Listed under “Members Present” but not present for the discussion and vote on this protocol for because of a Conflicting Interest. List the names of recused members in the vote. For example: “For: 7 Against: 3 Abstain: 2 Absent: 0 Recused: 2 (Evelyn Foxtrot, George India) Substitutions: 0.”
 - 5.8.14.6 Substitutions: Listed under “Members Present” When regular members and their alternate(s) are listed under “Members Present” and an alternate member substitutes for the regulator member, identify the name of the alternate to indicate which individual is serving as the voting member for this vote. May be deleted if there are no substitutions. For example: “For: 7 Against: 3 Abstain: 2 Absent: 0 Recused: 0 Substitutions: 1 (Evelyn Foxtrot substituted for George India).”
 - 5.8.15 Level of risk determined by the convened IRB: Minimal Risk or more than Minimal Risk.

- 5.8.16 Determinations and findings that require documentation: If the research involves waiver or alteration of consent, waiver of written documentation of consent, children, pregnant women, neonates, Prisoners, or adults with impaired decision-making capacity, include one of more of the “Determination/Protocol Specific Findings” tables in HRP-501 - TEMPLATE MINUTES or enter “See IRB records for this protocol” and ensure that the corresponding completed checklist is in the IRB records. Otherwise delete.
- 5.8.17 Rationale for a significant/non-significant device determination: Describe the rationale for the determination. Otherwise delete.
- 5.8.18 Modifications Required to Secure Approval: If this is the motion, complete the table with the required changes and corresponding reasons. Otherwise, delete.
- 5.8.19 Deferral/disapproval reasons and recommended changes: If this is the motion, complete the table with the recommendations and corresponding reasons. Otherwise, delete.
- 5.8.20 Suspension/termination reasons and recommended changes: If this is the motion, complete the table with the recommendations and corresponding reasons. Otherwise, delete.
- 5.8.21 Tabled reason: If the protocol was tabled, provide the reasons. Otherwise, delete.
- 5.9 Record the meeting end time.
- 5.10 Within 2 business days revise minutes for accuracy and provide them to the IRB chair or IRB manager for review and approval.
- 5.11 Once approved by the IRB chair or IRB manager, email them to:
 - 5.11.1 IO/OO or designee.
- 5.12 Provide the minutes to the IRB members at the next convened meeting for review and acceptance.

6 MATERIALS

- 6.1 HRP-501 - TEMPLATE MINUTES

7 REFERENCES

- 7.1 21 CFR §56.115(a)(2)
- 7.2 45 CFR §46.115(a)(2)
- 7.3 AAHRPP elements I-9, II.1.D, II.1.E, II.2.D, II.2.G, II.2.E-II.2.E.2, II.5.B