

SOP: IRB Meeting Minutes

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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 Administrative and current procedural updates.
- 2.2 Vote counts updated for better understanding and clarity.
- 2.3 Revised minute approval process to allow full IRB Committee approval.

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 the minutes.
- 3.5 The IRB writes minutes and makes them available for review within 30 business days (or reasonable time) of the meeting date.
- 3.6 Minutes maynot 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 "TEMPLATE MINUTES (HRP-501)" 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:
 - 5.2.1 Name.
 - 5.2.2 Status: E.g., chair, vice chair, scientific member, non-scientific member, unaffiliated member, or 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 on "DATABASE: IRB Roster (HRP-601)" or equivalent. 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 "DATABASE: IRB Roster (HRP-601)," then $10/2 = 5$ and the next whole number is 6. If there are 11 IRB members on the "DATABASE: IRB Roster (HRP-601)," 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.
- 5.6 Record the meeting start time.
- 5.7 List each business item that was discussed.
- 5.8 For each protocol reviewed record:
 - 5.8.1 Indicate the type of review.
 - 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)

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- 5.8.8 IND or IDE (indicate “none” if none)
- 5.8.9 See IRBNet for list of documents submitted
- 5.8.10 Notes: Summarize issues useful to understand the agenda item. For example, administrative comments or additional RNI comments provided to the researchers.
- 5.8.11 Consultant report: Summarize the key information provided by the consultant. Indicate “None” or 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, Approved with Modifications, 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, recused, or other. List the names of IRB members who abstained, 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 Attendance Total: The total number of voting members taken from the attendance roster.
 - 5.8.14.2 Vote Total: The total number of voting members present for the discussion and vote on this protocol.
 - 5.8.14.2.1 For: Voting for the motion.
 - 5.8.14.2.2 Against: Voting against the motion.
 - 5.8.14.2.3 Abstain: Present for the vote, but not voting “For” or “Against.” List the names of abstained members in the vote.
 - 5.8.14.3 Non-Voting:
 - 5.8.14.3.1 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.
 - 5.8.14.3.2 Recused: Listed under “Members Present” but not present for the discussion and vote on this protocol because of a Conflicting Interest. List the names of recused members in the vote.
 - 5.8.14.3.3 Other: Listed under “Members Present” but not voting on this protocol either because an alternate member is substituting for a regular member, or for any other reason.
 - 5.8.14.4 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 or indicate “None” if there are no substitutions.
- 5.8.15 Level of risk determined by the convened IRB: Minimal Risk or greater than Minimal Risk.
- 5.8.16 Determinations and findings that require documentation: If the criteria for approval has been met, the research involves a Conflict of Interest Management Plan, waiver or alteration of consent, waiver of written documentation of consent, children, pregnant women, neonates, Prisoners, or cognitively impaired adults, include one or more of the “Determination/Protocol Specific Findings” tables or equivalent text found in the “TEMPLATE MINUTES (HRP-501)” or include language referencing the IRB record as the basis for the determination. Ensure that the corresponding completed checklist or equivalent) is in the IRB records. Otherwise delete or indicate “None”.

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- 5.8.17 Rationale for a significant/non-significant device determination: Describe the rationale for the determination. Otherwise delete or indicate "None".
- 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 or indicate "None".
- 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 or indicate "None".
- 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 or indicate "None".
- 5.8.21 Tabled reason: If the protocol was tabled, provide the reasons. Otherwise, delete or indicate "None".
- 5.9 Record the meeting end time.
- 5.10 Attach the following documents to the approved minutes:
 - 5.10.1 List of exemptions granted.
 - 5.10.2 List of protocols granted approval using the expedited procedure.
 - 5.10.3 List of research approved with modifications to secure approval and granted approval by the chair or designee after confirmation that the modifications were made.
- 5.11 Provide to the staff member responsible for performing a quality improvement assessment, using "CHECKLIST: Minutes Quality Improvement Assessment (HRP-431)."
- 5.12 Revise minutes for accuracy and provide them to the IRB chair, Committee or Manager for review and approval.

6 MATERIALS

- 6.1 TEMPLATE: MINUTES (HRP-501)
- 6.2 CHECKLIST: Minutes Quality Improvement Assessment (HRP-431)

7 REFERENCES

- 7.1 21 CFR §56.115(a)(2)
- 7.2 45 CFR §46.115(a)(2)