



<b>SOP: IRB Meeting Minutes</b>				
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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 None
- 2.2 Revised who can approve minutes, developed process for revising minutes;

## **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 Executive Directory, HSRO.
- 3.4 IRB members may make corrections to the minutes.
- 3.5 The HSRO team members write minutes and make them available for review within 30 business days (or reasonable time) of the meeting date.
- 3.6 Minutes may not be altered unless the alteration is approved by the Executive Director, HSRO and the Chair who was present for the meeting.

## **4 RESPONSIBILITIES**

- 4.1 HSRO staff members carry out these procedures.

## **5 PROCEDURE**

- 5.1 Use the "TEMPLATE MINUTES (HRP-501)" or equivalent, to record observations at meetings.
- 5.2 Under "Attendance Table" or equivalent, record the following information about 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 unless the alternate is in voting status for every agenda item.
- 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 ID (indicate "none" if none)



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- 5.8.7 IND or IDE (indicate "none" if none)
- 5.8.8 Documents reviewed.
- 5.8.9 Notes: Summarize issues useful to understand the agenda item. For example, administrative comments or additional RNI comments provided to the researchers.
- 5.8.10 Consultant report: Summarize the key information provided by the consultant. Indicate "None" or delete if there was no consultant.
- 5.8.11 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."
- 5.8.12 Motion: Approved, Approved with Modifications, Deferred, Disapproved, Suspended, or Terminated, Unanticipated Problem Involving Risk to Subjects or Others; Non-Compliance, Serious Non-Compliance or Continuing Non-Compliance. For initial or continuing review add the period of approval to the motion. If the protocol was tabled, indicate this determination.
- 5.8.13 Vote: Record as the number of members for, against, abstaining, absent, recused, or other. List the names of IRB members who abstained, are listed on the attendance roster (Section 5.2) but are absent, or recused for the specific vote. Do not count votes of consultants. If both a regular IRB member and the alternate IRB member are present for the review of the agenda item, record the vote of just one.
  - 5.8.13.1 Attendance Total: The total number of voting members taken from the attendance roster.
  - 5.8.13.2 Vote Total: The total number of voting members present for the discussion and vote on this protocol.
    - 5.8.13.2.1 For: Voting for the motion.
    - 5.8.13.2.2 Against: Voting against the motion.
    - 5.8.13.2.3 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.



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- 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".
- 5.8.17 Document the rationale for a significant/non-significant device determination, when applicable. 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)