



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 None.
- 2.2 Revised who can approve minutes, developed process for revising minutes;
- 2.3 Revised to describe documentation relating to alternate members.
- 2.4 Reconciliation to Huron HRPP Toolkit 4.5, dated 12/10/2021

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 HRSO team members write minutes and make them available for review within 45 business days (or reasonable time) of the meeting date. Minutes are made available to the Institutional Official/ Organizational Official (IO/OO) in the electronic system.
- 3.6 Minutes that have been approved may not be altered unless the alteration is approved by the Director, HRSO and the Chair who was present for the meeting.

4 RESPONSIBILITIES

- 4.1 HRSO staff and IRB members carry out these procedures.

5 PROCEDURE

- 5.1 Execute the "Convene Meeting" activity
- 5.2 Use the "TEMPLATE MINUTES (HRP-501)" or equivalent, to record observations at meetings.
- 5.3 Under "Attendance Table" or equivalent, record the following information about each voting member (core members and alternates) present at the meeting at any time (Do not record members who do not vote on any agenda items under "Attendance Table"):
 - 5.3.1 Name.
 - 5.3.2 Status: E.g., chair, vice chair, scientific member, non-scientific member, .unaffiliated member, representative of vulnerable population (specify), prisoner representative, or alternate member.
 - 5.3.3 For alternate members who are substituting for a regular member, indicate the name of the regular member for whom the alternate member is substituting
 - 5.3.3.1 If both the regular and alternate member are present at the meeting, indicate the eProst number for the agenda items for which the alternate member will substitute.
 - 5.3.4 Whether the member was present by teleconference.
- 5.4 Record the total number of members in HRP-601 - DATABASE - IRB Roster. Exclude alternate members in this count unless the alternate is in voting status for every agenda item.
- 5.5 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.

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- 5.6 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.
- 5.7 Record the meeting start time.
- 5.8 For each submission reviewed record in the “Submit Committee Review” activity or “Submit RNI Committee Review” activity in eProst, as appropriate:
 - 5.8.1 Notes: Summarize issues useful to understand the agenda item. For example, administrative comments or additional RNI comments provided to the researchers.
 - 5.8.2 Record the motion and determination.
 - 5.8.3 Record the Risk Level and the reasons therefore.
 - 5.8.4 Recommended Changes and Reasons: If the motion is Modifications required to secure approval or deferral/disapproval, document the required changes and corresponding reasons.
 - 5.8.5 Controverted Issues and their Resolutions: 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.”
 - 5.8.6 Determinations and findings that require documentation If there are no determinations that require documentation, indicate “None.”
 - 5.8.7 RNI Determinations: Record the determination of unanticipated problem involving risks to subjects or others, suspension or termination of IRB approval, serious non-compliance, continuing non-compliance, non-compliance that is neither serious nor continuing, allegation of non-compliance with no basis in fact, or none of the above.
 - 5.8.8 RNI Considerations: Record requirements determined by the IRB.
 - 5.8.9 Supporting documents: For any determinations that require documentation, upload the appropriate checklist(s), or any other appropriate supporting documents.
 - 5.8.10 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.
 - 5.8.10.1 For: Voting for the motion.
 - 5.8.10.2 Against: Voting against the motion.
 - 5.8.10.3 Abstain: Present for the vote, but not voting “For” or “Against.”
 - 5.8.10.4 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.
 - 5.8.10.5 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.
 - 5.8.10.6 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.
 - 5.8.10.7 Substitutions: Listed under “Members Present” When regular members and their alternate(s) are listed under “Members Present” and an alternate member substitute 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.
- 5.9 Record the meeting end time.
- 5.10 Execute the “Prepare Minutes” activity and combine the attendee information with the generated submission-specific determinations.
- 5.11 Execute the “Close Meeting” activity

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5.12 Once the minutes are approved by the IRB chair, Committee or Manager, execute the "Approve Minutes" activity.

6 MATERIALS

6.1 HRP-601 - DATABASE - IRB Roster

6.2 HRP-431 - CHECKLIST - Minutes Quality Improvement Assessment

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