SOP: IRB Meeting Minutes

1. PURPOSE
   1. This procedure establishes the process to record minutes for convened meetings.
   2. The process begins when the meeting is called to order.
   3. The process ends when the minutes are approved by the IRB chair.
2. REVISIONS FROM PREVIOUS VERSION
   1. Addition of IRB meeting audio recording procedure
   2. Remove IRB Manager from approving the minutes
3. POLICY
   1. Minutes are to comply with regulatory and guidance requirements.
   2. Minutes are to record separate deliberations for each action.
   3. Minutes are officially approved on behalf of the IRB by the IRB chair.
   4. IRB members may make corrections to minutes.
   5. The IRB staff writes minutes and makes them available for review within three weeks of the meeting date OR by the committee at the next IRB meeting. Minutes are made available to the Institutional Official/Organizational Official (IO/OO).
   6. Minutes may not be altered by anyone including a higher authority once accepted by the convened IRB.
4. RESPONSIBILITIES
   1. IRB staff members carry out these procedures.
5. PROCEDURE
   1. Execute the “Convene Meeting” activity
   2. Record each voting member (regular members and alternates) present at the meeting at any time: (Do not record non-voting members under “Attendance Table”)
      1. Name.
      2. Status: e.g., chair, vice chair, scientific member, non-scientific member, unaffiliated member, representative of vulnerable population (specify), prisoner representative or alternate member.
      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.
      4. Whether the member was present by teleconference.
   3. Record the total number of members in HRP-601 - DATABASE - IRB Roster. Exclude alternate members in this count.
   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. 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.
   6. Record the meeting start time.
   7. For each submission reviewed record in the “Submit Committee Review” activity or “Submit RNI Committee Review” activity, as appropriate:
      1. Motion: Approved, Approved with Modifications, Deferred, Disapproved, Suspended, or Terminated. For initial or continuing review add the period of approval to the motion.
      2. Risk Level: Minimal Risk or more than Minimal Risk.
      3. Last Day of Approval Period: Record the study expiration date.
      4. Recommended Changes and Reasons: If the motion is Modifications required to secure approval or deferral/disapproval, complete the table with the required changes and corresponding reasons. If no recommended changes, indicate “None.”
      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.”
      6. 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 cognitively impaired adults, enter “See attached Supporting Documents” and ensure that the corresponding completed checklist is uploaded as a supporting document. If no determinations that require documentation, indicate “None.”
      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.
      8. RNI Considerations: Record requirements determined by the IRB, for example modification to the protocol or ask subjects to re-consent.
      9. Additional Information and Notes: Summarize issues useful to understand the agenda item. For example, a brief history of recent IRB actions
      10. Supporting documents: For any determinations that require documentation, upload the appropriate checklist(s), or any other appropriate supporting documents.
      11. 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.
          1. For: Voting for the motion.
          2. Against: Voting against the motion.
          3. Abstain: Present for the vote, but not voting “For” or “Against.”
          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. 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”
          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)”
      12. For an Unanticipated Problem Involving Risks to Subjects or Others, in the “Submit RNI Committee Review,” document the IRB’s determination as to whether a protocol or consent document modification is warranted, and if so, document the IRB’s determination as to whether previously enrolled subjects must be notified of the modification and, if so, when such notification must take place and how such notification must be documented.
   8. Record the meeting end time.
   9. Execute the “Prepare Minutes” activity and combine the attendee information with the generated submission-specific determinations.
   10. Within 2 business days revise minutes for accuracy and notify the IRB chair or IRB manager for review and approval.
   11. Once approved by the IRB chair, and execute the “Close Meeting” activity. Email minutes to:
       1. Executive Director, PPHS.
          1. Actions of particular interest will be brought to the attention of the Organizational Official by the Executive Director. All minutes will be made available to the Organizational Official upon request.
       2. IRB Members
   12. The minutes will show on the next agenda for that IRB committee under “Previous meetings with minutes for approval” for the IRB members at the next convened meeting to review and accept.
   13. Once accepted, execute the “Approve Minutes” activity to finalize the minutes.
6. MATERIALS
   1. HRP-601 - DATABASE - IRB Roster
7. REFERENCES
   1. 21 CFR §56.115(a)(2)
   2. 45 CFR §46.115(a)(2)
   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