



## 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 analyst or IRB manager

### 2 PREVIOUS VERSION

- 2.1 Revised from previous version dated 11/22/2018

### 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 Analyst or IRB Manager.
- 3.4 IRB members may request corrections to minutes.
- 3.5 The IRB Office staff writes minutes and makes them available for review after the IRB meeting. Minutes are made available to all the members and the Institutional Official/ Organizational Official (IO/OO).
- 3.6 Minutes may not be altered by anyone including a higher authority once approved.

### 4 RESPONSIBILITIES

- 4.1 IRB Office staff members carry out these procedures.

### 5 PROCEDURE

- 5.1 Execute the "Convene Meeting" activity.
- 5.2 Record each voting member (regular members and alternates) and non-voting alternate members 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, representative of vulnerable population (specify), prisoner representative, 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 For alternate members who are not voting, indicate that they are 'non-voting.'
  - 5.2.5 Whether the member was present by teleconference.
- 5.3 Record the total number of members on "DATABASE: IRB Roster (HRP-601)." 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 11 IRB members on the "DATABASE: IRB Roster (HRP-601)," then  $11/2=5.5$  and the next whole number is 6.
- 5.5 Record the meeting start and end time.
- 5.6 For each submission reviewed record in the "Submit Committee Review" activity or "Submit RNI Committee Review" activity, as appropriate:
  - 5.6.1 Motion: Approved, Modifications Required to Secure 'Approved', Deferred, Disapproved, Suspended, Not Human Research, Modifications Required to Secure 'Not Human Research', Human Research, Not Engaged, Modifications Required to Secure 'Human Research, Not Engaged.' For initial or continuing review add the period of approval to the motion, if the project is greater than minimal risk or FDA regulated.
  - 5.6.2 Risk Level: No greater than Minimal Risk or greater than Minimal Risk.



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- 5.6.3 If applicable, last Day of Approval Period: Record the study expiration date, if the study is greater than minimal risk or FDA regulated.
- 5.6.4 Recommended Changes and Reasons: If the motion is Modifications required to secure 'approved' or deferred or disapproved, complete the table with the required changes and corresponding reasons. If no recommended changes, indicate "None."
- 5.6.5 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."
- 5.6.6 Determinations and findings that require documentation: If the research involves waiver or alteration of consent, waiver of HIPAA authorization, 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."
- 5.6.7 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, none of the above, or additional information required before making a determination.
- 5.6.8 RNI Considerations: Record requirements determined by the IRB, for example modification to the protocol or ask subjects to re-consent.
- 5.6.9 Additional Information and Notes: Summarize issues useful to understand the agenda item. For example, a brief history of recent IRB actions
- 5.6.10 Supporting documents: For any determinations that require documentation, upload the appropriate checklist(s), or any other appropriate supporting documents.
- 5.6.11 Vote: Record as the number of members for, against, abstaining, absent, or recused. List the names of IRB members who were absent, abstained 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.
  - 5.6.11.1 For: Voting for the motion.
  - 5.6.11.2 Against: Voting against the motion.
  - 5.6.11.3 Abstain: Present for the vote, but not voting "For" or "Against."
  - 5.6.11.4 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 section or under additional information and notes.
  - 5.6.11.5 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 section or under additional information and notes.
  - 5.6.11.6 Substitutions: When regular members and their alternate(s) are listed under "Members Present" and an alternate member substitutes for the regular member, identify the name of the alternate to indicate which individual is serving as the voting member for this vote. May leave blank or write 'none' if there are no substitutions.
- 5.6.12 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.



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- 5.7 Execute the "Prepare Minutes" activity. Edit the document to include all required elements, such as attendee information and start and end time.
- 5.8 The meeting minutes will be available in the meeting workspace, for IRB members to review.
- 5.9 List of submissions granted approval using expedited procedures over the past 45 days, will be available in the meeting workspace.
- 5.10 Execute the "Approve Minutes" activity.

### 6 MATERIALS

- 6.1 None.

### 7 REFERENCES

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