

	<b>SOP: Meeting Minutes</b>		
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## 1 PURPOSE

- 1.1 This SOP 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 finalized and approved by the IRB Chair or HRPP Director.

## 2 REVISIONS FROM PREVIOUS VERSION

- 2.1 Revised from the 5/30/2017 version.
- 2.2

## 3 SOP Statement

- 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 HRPP Director.
- 3.4 IRB members may request corrections to minutes.
- 3.5 The IRB/HRPP staff writes minutes and makes the draft available for review within 21 days of the meeting date.
- 3.6 Approved minutes may not be altered by anyone including a higher authority once accepted by the convened IRB except as described in section 5.20 below.

## 4 RESPONSIBILITIES

- 4.1 IRB/HRPP staff members carry out these procedures.

## 5 PROCEDURE

- 5.1 Use the HRP-510 - TEMPLATE - Minutes or equivalent to record the minutes.
- 5.2 Record at the beginning of the minutes:
  - 5.2.1 Members present. Record the following information on IRB members present at any time during the meeting:
    - 5.2.1.1 Name
    - 5.2.1.2 Whether the IRB member is primary or an alternate
    - 5.2.1.3 Voting status (voting or non-voting)
    - 5.2.1.4 For alternate members who are substituting for a regular member, indicate the name of the regular member for whom the alternate member is substituting.
    - 5.2.1.5 Representative Capacity or other status: Status: E.g., chair, vice chair, scientific member, non-scientific member, unaffiliated member, representative of vulnerable population (specify), prisoner representative.
    - 5.2.1.6 Whether the IRB member attended by teleconference
- 5.3 Record the total number of members on the current IRB Roster. Exclude alternate members in this count.
- 5.4 Record the number of members required for quorum.
  - 5.4.1 Determine quorum by dividing the number of members by two and then add one. For example, if the total IRB membership is 10, then majority is 6 (half of 10 is 5, plus 1 equals 6). However, if the IRB has an odd number of members, then majority should be calculated by taking half of the total number of IRB members and rounding up to the next whole number. For example, if the IRB membership is 15, then majority is 8 (half of 15 is 7.5 and rounding up to the next whole number is 8).
- 5.5 Others present: Record the following information on individuals present at any time during the meeting:
  - 5.5.1 Name
  - 5.5.2 Role
- 5.6 Record the meeting start time.
- 5.7 Record a summary of any reports or educational activity presented.
- 5.8 Record a summary of any discussion of items unrelated to the review of specific research.
- 5.9 For each item related to specific research:
  - 5.9.1 Record the type of review: Initial, continuing, modification, reportable new information (RNI).

- 5.9.2 Record relevant information about the research:
- 5.9.2.1 Study Title
  - 5.9.2.2 Principal Investigator
  - 5.9.2.3 IRB number
  - 5.9.2.4 IND or IDE, if any
  - 5.9.2.5 Funding Source
  - 5.9.2.6 Documents reviewed
- 5.9.3 If any item is not acted upon, record the reason. Example: loss of quorum.
- 5.9.4 If a consultant provided a report, summarize the key information provided.
- 5.9.5 If there were controverted issues where IRB members expressed a difference of opinion summarize the issue. For each issue indicate the resolution or indicate that there was none.
- 5.9.6 If no controverted issues, indicate "None."
- 5.9.7 Record Additional Information and Notes: Summarize issues useful to understand the agenda item when needed. For example, a brief history of recent IRB actions.
- 5.10 For each submission reviewed record the motion as appropriate:
- 5.10.1 Motion:
    - 5.10.1.1 Approved,
    - 5.10.1.2 Modifications Required to Secure Approval,
    - 5.10.1.3 Deferred,
    - 5.10.1.4 Disapprove,
    - 5.10.1.5 Suspension, or
    - 5.10.1.6 Termination.
  - 5.10.2 For a motion of Approve or Modifications Required to Secure Approval related to an initial or continuing review add the following:
    - 5.10.2.1 The Approval Period
      - 5.10.2.1.1 Use HRP-302 - WORKSHEET - Approval Intervals to calculate approval period.
    - 5.10.2.2 Risk Level: Minimal Risk or more than Minimal Risk.
    - 5.10.2.3 Special determinations and study specific 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.
  - 5.10.3 For a motion of Approve or Modifications Required to Secure Approval related to a Modification:
    - 5.10.3.1 Risk Level: Minimal Risk or more than Minimal Risk.
    - 5.10.3.2 Any new special determinations and study specific findings not previously made that require documentation as indicated in section above.
    - 5.10.3.3 Any requirement for re-consent of subjects.
    - 5.10.3.4 If there are no special determinations that require documentation, indicate "None."
    - 5.10.3.5 Any rationale for any <Non-significant Risk Device> or <Significant Risk Device> determination.
  - 5.10.4 For the motion "Modifications Required to secure Approval" record the IRB's modifications required to secure approval and the reasons for those modifications.
  - 5.10.5 For the motion of "Deferred" record the IRB's reason and recommendations.
  - 5.10.6 For a motion of "Disapprove" record the IRB's reasons.
    - 5.10.6.1 If no recommended changes, indicate "None."
  - 5.10.7 For Reportable New Information (RNI) determinations record as appropriate:
    - 5.10.7.1 Unanticipated Problem Involving Risks to Subjects or Others,

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- 5.10.7.2 Suspension or Termination of IRB approval,
- 5.10.7.3 Serious Non-Compliance, Continuing Non-Compliance, Non-Compliance that is Neither Serious nor Continuing, Allegation of Non-Compliance with no Basis in Fact, or
- 5.10.7.4 None of the Above (Acknowledge)
- 5.10.8 RNI Considerations: Record requirements determined by the IRB, for example modification to the protocol or ask subjects to re-consent.
- 5.10.9 Record the vote as the number of members:
  - 5.10.9.1 For: Voting for the motion.
  - 5.10.9.2 Against: Voting against the motion.
  - 5.10.9.3 Abstain: Present for the vote, but not voting “For” or “Against.”
  - 5.10.9.4 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”
  - 5.10.9.5 Recused: Listed under “Members Present” on the minutes roster 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”
  - 5.10.9.6 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)”
- 5.11 Record the meeting end time.
- 5.12 Prepare minutes and combine the attendee information with the submission-specific determinations.
- 5.13 Revise and edit the minutes for accuracy.
- 5.14 Within 5-7 business days Send minutes to the HRPP Director or IRB Chair for review and approval.
- 5.15 Once approved by the HRPP Director or IRB Chair, upload the approved version into the electronic system.
- 5.16 Forward minutes to:
  - 5.16.1 Institutional Official or designee
  - 5.16.2 IRB Members
- 5.17 The IRB minutes, once approved, may not be altered by anyone except by the IRB Chairperson in concurrence with the HRPP Director (e.g., to correct minor or typographical errors).
  - 5.17.1 Any corrected minutes will be redistributed to the IRB and emailed as listed above.

## 6 MATERIALS

- 6.1 HRP-501 - TEMPLATE - Minutes
- 6.2 HRP-302 – WORKSHEET - Approval Intervals

## 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