Standard Operating Procedure (SOP)

SOP Number: SOP CW AHC 208	**SOP Name:** Minutes
Location: *Company-Wide Policies	**Responsible Department:** Research Services
Executive Owner: Executive Director of Research Services	**Original Creation Date:** 01/18/2022
Effective Date: 04/04/2022	**Review Date:** 02/12/2024

I. SCOPE: This standard operating procedure (SOP) applies to the Research Personnel and Institutional Review Board (IRB) staff members, chair, and committee members at AdventHealth.

II. PURPOSE: This procedure establishes the process to take IRB minutes. This procedure begins when the meeting is called to order and ends when the minutes are finalized.

III. QUALIFIED PERSONNEL: IRB staff members

IV. TRAINING: Not applicable

V. SUPPLIES & EQUIPMENT: Not applicable

VI. PROCESS/PROCEDURE:

A. Use the IRB Minutes Template to record minutes.

B. Record at the beginning of the minutes:

1. "Members Present": Record the following information on IRB members present at any time during the meeting and having voting status at least once during the meeting[i]:
   a) Name
   b) Status[ii]
   c) Whether the IRB member is an alternate
   d) Whether the IRB member attended by teleconference
2. "Others Present": Record the following information on individuals present at any time during the meeting who never have voting status:[iii]
   a) Name
   b) Role

C. Record the total number of regular members on the current IRB roster and the number of members required for quorum[iv].

D. If IRB members are present by teleconference, indicate whether they received all pertinent material before the meeting and were able to actively and equally participate in all discussions.

E. Record the time the meeting is called to order.

F. Record a summary of the discussion of items unrelated to the review of specific research.

G. For each item related to specific research:

1. Record the type of review[v].

2. Record relevant information about the research:
   a) Title
   b) Principal investigator
   c) IRB number
   d) IND or IDE number, if any
   e) HHS grant title and ID, if any
   f) Documents reviewed
3. When needed for clarity, summarize previous IRB actions.
4. If any item is not acted upon, record the reason[vi].
5. If a consultant provided an oral report, summarize the key information provided.
6. If there were any controverted issues (IRB members expressed a difference of opinion), summarize the issue, label as a controverted issue, and summarize the resolution, if any. If there were no controverted issues, record this.
7. Record the motion.
   a) For a motion of "Approve" or "Conditionally Approve" related to an initial or continuing review submission record:
      i. The approval period or that continuing review is not required. If continuing review is not required by HRP-400 WORKSHEET – Criteria for Approval but the IRB requires continuing review, document the rationale for requiring continuing review.
      ii. Whether the risk is Minimal Risk or greater than Minimal Risk
      iii. Any required checklist determinations along with study-specific findings supporting those determinations
      iv. Any rationale for any Non-significant Risk Device or Significant Risk Device determination
      v. Document that the IRB determined that the proposed research met the criteria for approval. In the case of a financial interest that is Related to the Research document instead that the IRB determined that proposed research with the management plan for the financial interest met the criteria for approval.
   b) For a motion of "Conditionally Approve" record the IRB's modifications required to secure approval and the reasons for those modifications.
      i. Document that the IRB determined that the proposed research with the requested modifications met the criteria for approval.
      ii. In the case of a financial interest that is Related to the Research document instead that the IRB determined that proposed research with the requested modifications and with the management plan for the financial interest met the criteria for approval.
   c) For a motion of "Defer" record the IRB's reasons and recommendations.

d) For a motion of "Disapprove" record the IRB's reasons.
e) For a motion of "Suspend" record the specific activities suspended and the IRB's recommendations, if any.
f) For a motion of "Lift Suspension" no other information needs to be recorded.
g) For a motion of "Terminate" record the IRB's reasons.

8. Record the vote as the numbers:
   a) "For": Voting for the motion.
   b) "Against": Voting against the motion.
   c) "Abstain": Present for the vote, but not voting "For" or "Against."
   d) "Absent": Not present for reasons other than a Conflicting Interest. Record the names of absent members (members in attendance at the meeting but absent from the room for the vote).
   e) "Recused": Not present for discussion and voting due to a Conflicting Interest. Record the names of recused members.
   f) Non-Voting Status: Present at the meeting but not in voting status (in voting status for some items but not in voting status for all items). Record the names of members present in non-voting status.

H. Record the time the meeting is adjourned.
I. Provide the minutes to the Meeting Chair for review and approval and provide to the IRB as an information item.
J. Provide approved minutes to the Organization Official and the IRB members who attended the meeting.
K. Upon request, AdventHealth makes IRB records (including minutes) available to clients provided they are relevant to the client. Such records may be excerpted or redacted to comply with AdventHealth's obligations to maintain confidentiality.

VII. DEFINITION(S):

For capitalized terms not defined in this SOP, refer to CW AHC 107 Definitions in Human Research.

For capitalized designations not defined in this policy, refer to CW AHC 103 Designations in Research

VIII. EXCEPTION(S):

See CW AHC 101 Research Oversight

IX. REFERENCE(S):

Not applicable

X. RELATED DOCUMENT(S) / ATTACHMENT(S):

- CW AHC 107 Definitions in Human Research
- CW AHC 103 Designations in Research
- CW AHC 101 Research Oversight

- CW AHC 108 Human Research Protection Program
- WORKSHEETS are located on the AdventHealth Research Institute website
  - HRP-400 WORKSHEET – Criteria for Approval
- Supporting Documentation
  - SOP CW AHC 208 - Exhibit A - IRB Minutes Template

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[i] If an IRB member has non-voting status for the entire meeting, list as an "Others Present."

[ii] For example: IRB Executive Chair, IRB vice-chair, scientific member, non-scientific member, unaffiliated member, pediatric experience, prisoner representative

[iii] This may include IRB members who are present for the meeting but never vote, consultants, non-IRB members, IRB staff, etc.

[iv] The whole number greater than one-half of the number of regular members

[v] For example: Initial, continuing, modification, Unanticipated Problem Involving Risks to Subjects or Others, Serious Noncompliance, Continuing Noncompliance, Suspension of IRB Approval, Termination of IRB Approval, study, site

[vi] For example: Loss of all non-scientific members, missing expertise, meeting ended early due to fire alarm.