

# Standard Operating Procedure (SOP)

<b>SOP #: 401.108</b>	<b>HRP-108 Minutes</b>
<b>Executive Owner: Vice President Research Operations</b>	<b>Effective Date: 6/11/2018</b>
	<b>Review Date: 9/19/2019</b>

<b>Scope</b>	This standard operating procedure (SOP) applies to the <Research Personnel> and Institutional Review Board (IRB) staff members, chair and committee members at AdventHealth Orlando.
<b>Purpose</b>	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.
<b>Qualified Personnel</b>	IRB Staff Members
<b>Training</b>	Not applicable.
<b>Supplies &amp; Equipment</b>	Not applicable.
<b>Procedure</b>	<ul style="list-style-type: none"> <li>A. Use the “Minutes (HRP-510)” template to record minutes.</li> <li>B. Record at the beginning of the minutes: <ul style="list-style-type: none"> <li>B.a. “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<sup>1</sup>: <ul style="list-style-type: none"> <li>B.a.i. Name.</li> <li>B.a.ii. Status<sup>2</sup></li> <li>B.a.iii. Whether the IRB member is an alternate</li> <li>B.a.iv. Whether the IRB member attended by teleconference.</li> </ul> </li> <li>B.b. “Others Present”: Record the following information on individuals present at any time during the meeting who never have voting status:<sup>3</sup> <ul style="list-style-type: none"> <li>B.b.i. Name.</li> <li>B.b.ii. Role</li> </ul> </li> </ul> </li> <li>C. Record the total number of regular members on the current IRB roster and the number of members required for quorum<sup>4</sup>.</li> <li>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</li> <li>E. Record the time the meeting is called to order.</li> <li>F. Record a summary of the discussion of items unrelated to the review of specific research.</li> </ul>

<sup>1</sup> If an IRB member has non-voting status for the entire meeting, list as an “Others Present.”

<sup>2</sup> For example: IRB chair, IRB vice-chair, scientific member, non-scientific member, unaffiliated member, pediatric experience, prisoner representative

<sup>3</sup> This may include IRB members who are present for the meeting but never vote, consultants, non-IRB members, HRPP staff, etc.

<sup>4</sup> The whole number greater than one-half of the number of regular members

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- G. For each item related to specific research:
- G.a. Record the type of review<sup>5</sup>
  - G.b. Record relevant information about the research:
    - G.b.i. Title
    - G.b.ii. Principal investigator
    - G.b.iii. IRB number
    - G.b.iv. IND or IDE number, if any
    - G.b.v. HHS grant title and ID, if any
    - G.b.vi. Documents reviewed
  - G.c. When needed for clarity, summarize previous IRB actions.
  - G.d. If any item is not acted upon, record the reason<sup>6</sup>.
  - G.e. If a consultant provided an oral report, summarize the key information provided.
  - G.f. 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.
    - G.f.i. If there were no controverted issues, record this.
  - G.g. Record the motion.
    - G.g.i. For a motion of “Approve” or “Conditionally Approve” related to an initial or continuing review submission record:
      - G.g.i.1. The approval period or that continuing review is not required.
        - G.g.i.1.1. If continuing review is not required by “WORKSHEET: Criteria for Approval (HRP-400)” but the IRB requires continuing review, document the rationale for requiring continuing review.
      - G.g.i.2. Whether the risk is <Minimal Risk> or greater than <Minimal Risk>
      - G.g.i.3. Any required checklist determinations along with study-specific findings supporting those determinations
      - G.g.i.4. Any rationale for any <Non-significant Risk Device> or <Significant Risk Device> determination

<sup>5</sup> 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

<sup>6</sup> For example: Loss of all non-scientific members, missing expertise, meeting ended early due to fire alarm

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- G.g.i.5. Document that the IRB determined that the proposed research met the criteria for approval.
  - G.g.i.5.1. 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.
- G.g.ii. For a motion of “Conditionally Approve” record the IRB’s modifications required to secure approval and the reasons for those modifications.
  - G.g.ii.1. Document that the IRB determined that the proposed research with the requested modifications met the criteria for approval.
    - G.g.ii.1.1. 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.
- G.g.iii. For a motion of “Defer” record the IRB’s reasons and recommendations.
- G.g.iv. For a motion of “Disapprove” record the IRB’s reasons.
- G.g.v. For a motion of “Suspend” record the specific activities suspended and the IRB’s recommendations, if any.
- G.g.vi. For a motion of “Lift Suspension” no other information needs to be recorded.
- G.g.vii. For a motion of “Terminate” record the IRB’s reasons.
- G.h. Record the vote as the numbers:
  - G.h.i. “For”: Voting for the motion.
  - G.h.ii. “Against”: Voting against the motion
  - G.h.iii. “Abstain”: Present for the vote, but not voting “For” or “Against”
  - G.h.iv. “Absent”: Not present for reasons other than a <Conflicting Interest>

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- G.h.iv.1. Record the names of absent members (members in attendance at the meeting, but absent from the room for the vote)
- G.h.v. “Recused”: Not present for discussion and voting due to a <Conflicting Interest>
  - G.h.v.1. Record the names of recused members
- G.h.vi. 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)
  - G.h.vi.1. 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 [Organizational Official] and the IRB members who attended the meeting.
- K. Upon request AdventHealth Orlando makes IRB records (including minutes) available to clients provided they are relevant to the client. Such records may be excerpted and/or redacted to comply with AdventHealth Orlando’s obligations to maintain confidentiality.

**Definition(s)** IRB: Institutional Review Board

**Reference(s)** Not applicable.

**Related Documents** Not applicable.

**Keywords** IRB, institutional review board, IRB member, minutes