

SOP: Minutes

Document No.:	Edition No.:	Effective Date:	Page:
HRP-108	003	01 APR 20222	Page 1 of 3

1. PURPOSE

- 1.1. This procedure establishes the process to take IRB minutes.
- 1.2. This procedure begins when the meeting is called to order.
- 1.3. This procedure ends when the minutes are finalized.

2. POLICY

- 2.1. None

3. RESPONSIBILITY

- 3.1. HRPP staff members carry out these procedures.

4. PROCEDURE

- 4.1. Use the minutes template to record minutes.
- 4.2. Record at the beginning of the minutes:
 - 4.2.1. Record the following information on IRB members present at any time during the meeting and having voting status at least once during the meeting¹:
 - 4.2.1.1. Name.
 - 4.2.1.2. Status²
 - 4.2.1.3. Whether the IRB member is an alternate
 - 4.2.1.4. Whether the IRB member attended by teleconference.
 - 4.2.2. Record the following information on individuals present at any time during the meeting who never have voting status:³
 - 4.2.2.1. Name.
 - 4.2.2.2. Role
- 4.3. If IRB members are present by teleconference, indicate whether they received all pertinent material before the meeting and could actively and equally participate in all discussions
- 4.4. Record the time the meeting is called to order.
- 4.5. For each item related to specific research:
 - 4.5.1. Record the type of review⁴
 - 4.5.2. Record relevant information about the research:
 - 4.5.2.1. Title
 - 4.5.2.2. Principal investigator
 - 4.5.2.3. IRB number
 - 4.5.3. When needed for clarity, summarize previous IRB actions.
 - 4.5.4. If any item is not acted upon, record the reason⁵.
 - 4.5.5. If a consultant provided an oral report, summarize the key information provided.
 - 4.5.6. 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.

¹ If an IRB member has non-voting status for the entire meeting, list as an "Others Present."

² For example: IRB chair, IRB vice-chair, scientific member, non-scientific member, unaffiliated member

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

⁴ For example: Initial, continuing, amendment, new information

⁵ For example: Loss of all non-scientific members, missing expertise, meeting ended early due to fire alarm

SOP: Minutes

Document No.:	Edition No.:	Effective Date:	Page:
HRP-108	003	01 APR 20222	Page 2 of 3

- 4.5.6.1. If there were no controverted issues, record this.
- 4.5.7. Record the motion.
 - 4.5.7.1. For a motion of “Approve” or “Conditionally Approve” related to an initial or continuing review submission record:
 - 4.5.7.1.1. The period of approval or that continuing review is not required.
 - 4.5.7.1.1.1. 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 review⁶
 - 4.5.7.1.2. Whether the risk is <Minimal Risk> or greater than <Minimal Risk>
 - 4.5.7.1.3. Any required checklist determinations along with study-specific findings supporting those determinations
 - 4.5.7.1.4. Any rationale for any <Non-significant Risk Device> or <Significant Risk Device> determination
 - 4.5.7.1.5. The IRB’s determination regarding the criteria for approval
 - 4.5.7.2. For a motion of “Conditionally Approve” record the IRB’s modifications required to secure approval and the reasons for those modifications.
 - 4.5.7.3. For a motion of “Defer” record the IRB’s reasons and recommendations.
 - 4.5.7.4. For a motion of “Disapprove” record the IRB’s reasons.
 - 4.5.7.5. For a motion of “Suspend” record the specific activities suspended and the IRB’s recommendations, if any.
 - 4.5.7.6. For a motion of “Lift Suspension” no other information needs to be recorded.
 - 4.5.7.7. For a motion of “Terminate” record the IRB’s reasons.
- 4.5.8. Record the vote as the numbers:
 - 4.5.8.1. “For”: Voting for the motion.
 - 4.5.8.2. “Against”: Voting against the motion
 - 4.5.8.3. “Abstain”: Present for the vote, but not voting “For” or “Against”
 - 4.5.8.4. “Absent”: Not present for reasons other than a <Conflicting Interest>
 - 4.5.8.4.1. Record the names of absent members (members in attendance at the meeting, but absent from the room for the vote)
 - 4.5.8.5. “Recused”: Not present for discussion and voting due to a <Conflicting Interest>
 - 4.5.8.5.1. Record the names of recused members
 - 4.5.8.6. 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)

⁶ When research is FDA-regulated and subject to the <Revised Rule>, the IRB’s rationale for requiring continuing review is that the research is FDA-regulated.

SOP: Minutes

Document No.:	Edition No.:	Effective Date:	Page:
HRP-108	003	01 APR 20222	Page 3 of 3

4.5.8.6.1. Record the names of members present in non-voting status

4.6. When applicable, note the determinations made by the Board with regard to Worksheets and Checklists. Note any disagreements.

4.6.1. The Worksheets and Checklists are then marked accordingly and stored within the minutes for the applicable review.

4.7. Record the time the meeting is adjourned.

4.8. Provide the minutes to the <Meeting Chair> for review and approval, and provide to the IRB as an information item.

4.9. Provide approved minutes to the [Organizational Official].

5. REFERENCES

5.1. 21 CFR §56.115

5.2. 45 CFR §46.115