



SOP: Minutes

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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, modification, new information, study, site

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



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- 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.



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

- 4.6. Record the time the meeting is adjourned.
- 4.7. Provide the minutes to the <Meeting Chair> for review and approval, and provide to the IRB as an information item.
- 4.8. Provide approved minutes to the [Organizational Official].

5. REFERENCES

- 5.1. 21 CFR §56.115
- 5.2. 45 CFR §46.115