



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 (HRP-510)" template to record minutes for each individual agenda item and the "Minutes Cover Sheet (HRP-511)" to record attendance and general meeting information.
- 4.2. Complete the Minutes Cover Sheet.
 - 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
 - 4.2.3. Record the total number of regular members on the current IRB roster and the number of members required for quorum⁴.
 - 4.2.4. 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
 - 4.2.5. Record the time the meeting is called to order.
 - 4.2.6. Record a summary of the discussion of items unrelated to the review of specific research.
- 4.3. For each item related to specific research:
 - 4.3.1. Record the type of review⁵
 - 4.3.2. Record relevant information about the research:

¹ If an IRB member has non-voting status for the entire meeting, list under 4.2.2

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

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

⁴ The whole number greater than one-half of the number of regular members

⁵ 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



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- 4.3.2.1. Title
- 4.3.2.2. Principal investigator
- 4.3.2.3. IRB number
- 4.3.3. When needed for clarity, summarize previous IRB actions.
- 4.3.4. If any item is not acted upon, record the reason⁶.
- 4.3.5. If a consultant provided an oral report, summarize the key information provided.
- 4.3.6. 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.
 - 4.3.6.1. If there were no controverted issues, record this.
- 4.3.7. Record the motion.
 - 4.3.7.1. For a motion of “Approve” or “Conditionally Approve” related to an initial or continuing review submission record:
 - 4.3.7.1.1. The approval period
 - 4.3.7.1.2. Whether the risk is <Minimal Risk> or greater than <Minimal Risk>
 - 4.3.7.1.3. Any required checklist determinations along with study-specific findings supporting those determinations
 - 4.3.7.1.4. Any rationale for any <Non-significant Risk Device> or <Significant Risk Device> determination
 - 4.3.7.2. For a motion of “Conditionally Approve” record the IRB’s modifications required to secure approval and the reasons for those modifications.
 - 4.3.7.3. For a motion of “Defer” record the IRB’s reasons and recommendations.
 - 4.3.7.4. For a motion of “Disapprove” record the IRB’s reasons.
 - 4.3.7.5. For a motion of “Suspend” record the specific activities suspended and the IRB’s recommendations, if any.
 - 4.3.7.6. For a motion of “Lift Suspension” no other information needs to be recorded.
 - 4.3.7.7. For a motion of “Terminate” record the IRB’s reasons.
- 4.3.8. Record the vote as the numbers:
 - 4.3.8.1. “Total”: Total number of members voting
 - 4.3.8.2. “For”: Voting for the motion.
 - 4.3.8.3. “Against”: Voting against the motion
 - 4.3.8.4. “Abstain”: Present for the vote, but not voting “For” or “Against”
 - 4.3.8.5. “Substitutions/Absences”: Alternates voting for other members who are not present for the vote, or, if no one is available to alternate for the person absent, the absence of that member.
 - 4.3.8.5.1. Record the names of the voting alternates and the names of the absent members for whom they are voting.
 - 4.3.8.6. “Recused”: Not present for discussion and voting due to a <Conflicting Interest>
 - 4.3.8.6.1. Record the names of recused members
- 4.4. Record the time the meeting is adjourned.

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



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- 4.5. Provide the minutes to the <Meeting Chair> for review and approval, and provide to the IRB members who attended the meeting as an information item.
- 4.6. Provide approved minutes to the [Organizational Official] upon request.

5. REFERENCES

- 5.1. 21 CFR §56.115(a)(2)
- 5.2. 45 CFR §46.115(a)(2)