

## 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.
- 4.2. Record at the beginning of the minutes:
  - 4.2.1. "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<sup>1</sup>:
    - 4.2.1.1. Name.
    - 4.2.1.2. Status<sup>2</sup>
    - 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. "Others Present": Record the following information on individuals present at any time during the meeting who never have voting status:<sup>3</sup>
    - 4.2.2.1. Name.
    - 4.2.2.2. Role
- 4.3. Record the total number of regular members on the current IRB roster and the number of members required for quorum<sup>4</sup>.
- 4.4. 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
- 4.5. Record the time the meeting is called to order.
- 4.6. Record a summary of the discussion of items unrelated to the review of specific research.
- 4.7. For each item related to specific research:
  - 4.7.1. Record the type of review<sup>5</sup>
  - 4.7.2. Record relevant information about the research:
    - 4.7.2.1. Title
    - 4.7.2.2. Principal investigator
    - 4.7.2.3. IRB number
    - 4.7.2.4. IND or IDE number, if any

<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

<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

<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

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- 4.7.2.5. HHS grant title and ID, if any
- 4.7.2.6. Documents reviewed
- 4.7.3. When needed for clarity, summarize previous IRB actions.
- 4.7.4. If any item is not acted upon, record the reason<sup>6</sup>.
- 4.7.5. If a consultant provided an oral report, summarize the key information provided.
- 4.7.6. 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.
  - 4.7.6.1. If there were no controverted issues, record this.
- 4.7.7. Record the motion.
  - 4.7.7.1. For a motion of “Approve” or “Modifications Required to Secure Approval” related to an initial or continuing review submission record:
    - 4.7.7.1.1. The approval period
    - 4.7.7.1.2. Whether the risk is <Minimal Risk> or greater than <Minimal Risk>
    - 4.7.7.1.3. Any required checklist determinations along with study-specific findings supporting those determinations
    - 4.7.7.1.4. Any rationale for any <Non-significant Risk Device> or <Significant Risk Device> determination
  - 4.7.7.2. For a motion of “Modifications Required to Secure Approval” record the IRB’s modifications required to secure approval and the reasons for those modifications.
  - 4.7.7.3. For a motion of “Defer” record the IRB’s reasons and recommendations.
  - 4.7.7.4. For a motion of “Disapprove” record the IRB’s reasons.
  - 4.7.7.5. For a motion of “Suspend” record the specific activities suspended and the IRB’s recommendations, if any.
  - 4.7.7.6. For a motion of “Lift Suspension” no other information needs to be recorded.
  - 4.7.7.7. For a motion of “Terminate” record the IRB’s reasons.
- 4.7.8. Record the vote as the numbers:
  - 4.7.8.1. “For”: Voting for the motion.
  - 4.7.8.2. “Against”: Voting against the motion
  - 4.7.8.3. “Abstain”: Present for the vote, but not voting “For” or “Against”
  - 4.7.8.4. “Absent”: Not present for reasons other than a <Conflicting Interest>
    - 4.7.8.4.1. Record the names of absent members (members in attendance at the meeting, but absent from the room for the vote)
  - 4.7.8.5. “Recused”: Not present for discussion and voting due to a <Conflicting Interest>
    - 4.7.8.5.1. Record the names of recused members
  - 4.7.8.6. 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)
    - 4.7.8.6.1. Record the names of members present in non-voting status

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

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- 4.8. Record the time the meeting is adjourned.
- 4.9. Provide the minutes to the <Meeting Chair> or [HRPP Administrator] for review and approval.
- 4.10. Make approved minutes available to:
  - 4.10.1. The [Organizational Official] and the IRB members who attended the meeting.
  - 4.10.2. The Director, Office of Clinical Research.
  - 4.10.3. The Quality Improvement Manager, Office of Clinical Research.
- 4.11. IRB members have 7 days to review the minutes. If no comments or revisions are received within 7 days, the minutes will be considered accepted.
- 4.12. Attach the following documents to the approved minutes:
  - 4.12.1. List of exemptions granted.
  - 4.12.2. List of protocols granted approval using the expedited procedure.

## 5. REFERENCES

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