

| SOP: MINUTES | | | |
|---------------------|--------------|-----------------|-------------|
| Document No.: | Edition No.: | Effective Date: | Page: |
| CM-108 | 001 | 1 May 2015 | Page 1 of 2 |

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. "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:
 - 4.2.1.1 Name
 - 4.2.1.2 Status
 - 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:
 - 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.
- 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.
 - 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
 - 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.
 - 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.

| SOP: MINUTES | | | |
|---------------|--------------|-----------------|-------------|
| Document No.: | Edition No.: | Effective Date: | Page: |
| CM-108 | 001 | 1 May 2015 | Page 2 of 2 |

- 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” “Absent”:
 - 4.7.8.4 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
- 4.8. Record the time the meeting is adjourned.
- 4.9. Provide the minutes to the <Meeting Chair> for review and approval, and provide to the convened IRB as an information item.
- 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.

5. REFERENCES

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