



IBC Title:	IBC Meeting Minutes		
SOP #106	IBC	IBC Approval Date:	January 11, 2021

1 SCOPE

This SOP applies to administrative processes of making and the approval of minutes for all regular and special IBC meetings.

2 PURPOSE

- 2.1 This SOP establishes the process to take minutes of all meetings of the IBC.
- 2.2 This process begins when the meeting is called to order.
- 2.3 This process ends when a set of meeting minutes are finalized and approved by the IBC.

3 RESPONSIBILITIES

- 3.1 IBC members (primary and alternate) carry out this procedure.

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 IBC 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 IBC member is an alternate; and
 - 4.2.1.4. Whether the IBC 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. State the total number of regular members on the current IBC roster and the number of members required for quorum.
- 4.4. If IBC 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:
 - Title
 - Principal investigator
 - IBC number
 - Documents reviewed
 - 4.7.3. When needed for clarity, summarize previous IBC 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 no controverted issues, record it. If there were any controverted issues (IBC members expressed a difference of opinion), summarize the issue, label as a controverted issue, and summarize the resolution, if any.
- 4.7.7. Record each motion.
- 4.7.7.1. For a motion of "Approve" or "Conditionally Approve" related to an initial or continuing review submission, record the approval period and the findings supporting these determinations.
- 4.7.7.2. For a motion of "Conditionally Approve," record the IBC's modifications required to secure approval and the reasons for those modifications.
- 4.7.7.3. For a motion of "Defer" record the IBC's reasons and recommendations.
- 4.7.7.4. For a motion of "Disapprove," record the IBC's reasons.
- 4.7.7.5. For a motion of "Tabled," record the specific activities suspended and the IBC's recommendations, if any.
- 4.7.8. Record the vote as the numbers:
- "For": Voting for the motion.
 - "Against": Voting against the motion
 - "Abstain": Present for the vote, but not voting "For" or "Against"
 - "Absent": Not present for reasons other than a conflict of interest
 - Record the names of absent members (members in attendance at the meeting, but sent absent from the room for the vote)
 - "Recused": Not present for discussion and voting due to a conflict of interest
 - Record the names of recused members
 - 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)
 - Record the names of members present in non-voting status
- 4.8. Record the time the meeting is adjourned.
- 4.9. Provide the draft copy of the minutes to the Meeting Chair and IO for review. Forward the final copy to convened IBC members for review.
- 4.10. Include approval of minutes as an agenda item in the following IBC meeting and vote for the approval of minutes.

5 REFERENCED MATERIALS

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

6 VERSION HISTORY

- 6.1 Version 1.0.