	SOP: Meeting Minutes	
	Section II: IRB Members and Meetings	
	Number	Effective Date
	IRB II-007	9/13/2025

1. PURPOSE

- 1.1. This SOP outlines the process to take minutes for convened meetings.
- 1.2. The process begins when the meeting is called to order.
- 1.3. The process concludes when the minutes are finalized and approved at the next convened meeting.

2. REVISION FROM PREVIOUS VERSIONS

- 2.1. None

3. SOP STATEMENT

- 3.1. Minutes are to comply with regulatory and guidance requirements.
- 3.2. Minutes are to record separate deliberations for each action.
- 3.3. Minutes are officially approved at a subsequent convened meeting.
- 3.4. IRB members may provide corrections to minutes.
- 3.5. The research compliance staff assigned to the IRB or designee writes minutes and will strive to make the draft available to IRB Chair for review within 10-14 days of the meeting date.
- 3.6. Approved minutes may not be altered by anyone including a higher authority once accepted by the convened IRB except as described in section 5.15 below.

4. RESPONSIBILITIES

- 4.1. The research compliance staff assigned to the IRB carries out these procedures.

5. PROCEDURE

- 5.1. Use the TAMUK minutes template found in the Cayuse electronic system to record the minutes.
- 5.2. Record at the beginning of the minutes:
 - 5.2.1. Members present. Record the following information on IRB members present at any time during the meeting:
 - 5.2.1.1. Name or Identification number
 - 5.2.1.2. Whether the IRB member is scientist or non-scientist
 - 5.2.1.3. Whether the IRB member is a community member or a member of TAMUK
 - 5.2.1.4. Their affiliation with TAMUK
 - 5.2.2. Members not present: Record the following information on IRB members not present at any time during the meeting:
 - 5.2.2.1. Name
 - 5.2.2.2. Whether the IRB member is scientist or non-scientist

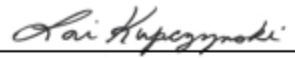
- 5.2.2.3. Whether the IRB member is a community member or a member of TAMUK
- 5.2.2.4. Their affiliation with TAMUK
- 5.2.3. Others present. Record the following information on individuals present at any time during the meeting:
 - 5.2.3.1. Name
 - 5.2.3.2. Their role
 - 5.2.3.3. Their affiliation with TAMUK
- 5.2.4. For alternate members who are substituting for a regular member, indicate the name of the regular member for whom the alternate member is substituting.
- 5.3. Record the total number of members on the current IRB Roster. Exclude alternate members in this count.
- 5.4. Record the number of members required for quorum.
 - 5.4.1. Determine quorum by dividing the number of members by two and then add one, or for an odd number of members, then majority should be calculated by taking half of the total number of IRB members and rounding up to the next whole number.
- 5.5. Record the meeting start time.
- 5.6. Record approval of previous minutes from last convened meeting.
- 5.7. Record the protocols that are being presented. The following items are reviewed for each study presented:
 - 5.7.1. Record the type of review: Initial, continuing, or modification.
 - 5.7.2. Record relevant information about the research:
 - 5.7.2.1. IRB number
 - 5.7.2.2. Principal Investigator(s) and Co-Investigator(s)
 - 5.7.2.3. Study Title
 - 5.7.2.4. Purpose and Procedure
 - 5.7.2.5. Discussion
 - 5.7.2.6. Controverted Issues
 - 5.7.2.7. Review of approval criteria
 - 5.7.2.8. Primary reviewer presenting the protocol
 - 5.7.3. If any item is not acted upon, record the reason. Example: loss of quorum.
 - 5.7.4. If there were controverted issues where IRB members expressed a difference of opinion, summarize the issue. For each issue, indicate the resolution or indicate that there was none.
 - 5.7.5. If no controverted issues, indicate "None."
 - 5.7.6. Record Additional Information and Notes: Summarize issues useful to understand the agenda item when needed. For example, a brief history of recent IRB actions.
- 5.8. For each submission reviewed record the motion as appropriate:

- 5.8.1. Motion:
 - 5.8.1.1. Approved,
 - 5.8.1.2. Modifications Required to Secure Approval (minor stipulations),
 - 5.8.1.3. Deferred,
 - 5.8.1.4. Disapproved,
 - 5.8.1.5. Suspension, or
 - 5.8.1.6. Closed.
- 5.8.2. For the motion “Modifications Required to Secure Approval” (minor stipulations), record the IRB’s modifications required to secure approval and the reasons for those modifications.
- 5.8.3. For the motion of “Deferred,” record the IRB’s reason and recommendations.
- 5.8.4. For a motion of “Not approved,” record the IRB’s reasons.
- 5.8.5. For a motion of “Suspension,” record the IRB’s reasons.
- 5.8.6. For a motion of “Closed,” record the IRB’s reasons.
- 5.8.7. Record the vote as the number of members:
 - 5.8.7.1. For: Voting for the motion.
 - 5.8.7.2. Against: Voting against the motion.
 - 5.8.7.3. Abstain: Present for the vote, but not voting “For” or “Against.”
 - 5.8.7.4. Absent: Listed under Members Present on the minutes roster but not present for the discussion and vote on a protocol.
 - 5.8.7.5. This protocol for reasons other than a Conflict of Interest. List the names of absent members in the vote. For example: “For: 7, Against: 3, Abstain: 2, Absent: 2 (Jane Bravo, Charlie Delta), Recused: 0, Substitutions: 0”
 - 5.8.7.6. Recused: Listed under Members Present on the minutes roster but not present for the discussion and vote on this protocol because of a Conflict of Interest. List the names of recused members in the vote. For example: “For: 7, Against: 3, Abstain: 2, Absent: 0, Recused: 2 (Evelyn Foxtrot, George India), Substitutions: 0”
 - 5.8.7.7. Substitutions: Listed under Members Present on the minutes roster. When a regular member is not present and an alternate member substitutes for the regular member, identify the name of the alternate to indicate which individual is serving as the voting member for this vote. May be deleted if there are no substitutions. For example: “For: 7, Against: 3, Abstain: 2, Absent: 0, Recused: 0, Substitutions: 1 (Evelyn Foxtrot substituted for George India)”
- 5.9. Record any announcements.
- 5.10. Record the meeting end time.
- 5.11. Record next scheduled meeting date.

- 5.12. Prepare minutes, including revision and edits, for accuracy in the Cayuse electronic system.
- 5.13. Notify IRB Chair that minutes are ready for review and revision with a 5 to 7 day deadline to return.
- 5.14. Finalize minutes in the Cayuse electronic system and notify all IRB members they are ready for review and approval at next convened meeting.
 - 5.14.1. The Chair is not required to sign the minutes.
- 5.15. The IRB minutes, once approved, cannot be altered by anyone except by the IRB Chair or research compliance staff assigned to the IRB (e.g., minor editorial changes, such as the correction of typos, as approved by the IRB Chair).

6. REFERENCES

- 6.1. [21 CFR §56.115](#)(a)(2).
- 6.2. [45 CFR §46.115](#)(a)(2).

Approved by: 
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