TEXAS A&M UNIVERSITY KINGSVILLE	**SOP: IRB Meeting Attendance – Quorum Monitoring & Meeting Conduct – Committee Review**	
	Section II: IRB Members and Meetings	
	Number	Effective Date
	IRB II-006	9/13/2025

1. PURPOSE

1.1. This SOP outlines the process to monitor quorum and conduct convened IRB meetings.

1.2. The process begins when the meeting is called to order.

1.3. The process concludes when the meeting is adjourned.

2. REVISION FROM PREVIOUS VERSIONS

2.1. None

3. SOP STATEMENT

3.1. The IRB meets as needed for Convened Protocol Reviews.

3.2. The IRB may meet more when needed.

3.3. No limit is placed on the volume of agenda items reviewed.

3.4. The IRB Chair is responsible to:

3.4.1. Lead the IRB meeting

3.4.2. Facilitate IRB reviews done by primary reviewer

3.4.3. Fill out the IRB Convened Board Protocol Checklist

3.4.4. Ensure TAMUK SOP: Meeting Attendance – Quorum Monitoring & Meeting Conduct – Committee Review (IRB SOP II-006) is followed

3.4.5. Monitor the IRB's decisions for consistency

3.4.6. Ensure that IRB members are free to participate in discussions

3.4.7. Ensure that IRB members attending by video or teleconference can actively and equally participate in all discussions, if applicable

3.5. A designated substitute may carry out the responsibilities of the Chair when required.

3.6. IRB members are to know the definition of Conflict of Interest and to disclose any Conflict of Interest.

3.7. IRB members must maintain confidentiality of IRB deliberations.

3.8. All IRB members who are part of quorum may vote, including IRB Chair.

3.9. The IRB Chair votes as a regular member.

3.10. Absent IRB members may submit written comments within the Cayuse electronic system but may not vote.

3.11. The IRB reviews research in accordance with the applicable regulatory criteria for approval.

3.12. Substantive changes or requirements, requests for more information for IRB consideration, and other issues related to the criteria for approval require review and approval by the convened IRB and will be tabled until the next Convened meeting.

3.13. Administrative, minor, or prescriptive changes or requirements (modifications required to secure approval) may be reviewed for approval by the IRB Chair and a primary reviewer.

4. RESPONSIBILITIES

4.1. The research compliance staff assigned to the IRB or designee carries out the quorum monitoring.

4.2. Primary reviewer leads IRB members through consideration and discussions of the regulatory criteria for approval.

4.3. The IRB Chair or designee carries out these procedures.

5. PROCEDURE

5.1. Meeting Attendance – Quorum Monitoring:

5.1.1. When a member leaves the meeting room for any reason, or a member attending by video or teleconference disconnects (including a Conflict of Interest), the IRB Chair and/or the research compliance staff assigned to the IRB determine that the meeting continues to be appropriately convened by meeting the quorum requirements.

5.1.1.1. If quorum is lost during a meeting, the IRB cannot take votes until the quorum is restored.

5.1.1.2. If quorum is lost during a meeting and cannot be restored, remaining agenda items will be moved to the next available convened meeting.

5.1.1.3. When IRB members review research that involves vulnerable subjects, at least one individual who is knowledgeable about or experienced in working with such subjects will be present at the meeting.

5.1.1.4. Alternate IRB members serve the same function as other IRB members, except that if the alternate IRB member and the regular IRB member for whom the alternate member is substituting are both present, only the regular member may vote.

5.1.1.5. A non-scientific member must be present in order for the meeting to proceed. That member may be a full member of the IRB or an alternate.

5.1.1.6. There must be half plus one board members present (this includes the non-scientific/non-affiliated member) in order for the meeting to take place. If an alternate cannot be found and quorum is not met, then the meeting will be tabled until the next IRB meeting.

5.2. Meeting Conduct – Committee Review:

5.2.1. Call the meeting to order.

5.2.2. Ask IRB members whether anyone has a Conflict of Interest in any item on the agenda and note the response.

5.2.3. For each item on the agenda involving review:

5.2.3.1. Table the item upon notification from IRB research compliance staff assigned to the IRB that quorum requirements are not met.

5.2.3.2. If any IRB members have a Conflict of Interest, permit the IRB to ask clarification questions, then require those members to leave the room or, if participating remotely, to disconnect or be placed on hold during discussion and voting.

5.2.3.3. Ask the primary reviewer to present their review to the IRB and provide discussion of the criteria for approval through the IRB Convened Board Protocol Checklist.

5.2.3.4. For new information (Unanticipated Problem Involving Risks to Subjects or Others, Serious Non-Compliance, Continuing Non-Compliance, Suspension of IRB Approval, or Termination of IRB Approval), the IRB Chair leads the convened IRB through a discussion of what actions are needed, if any, to protect subjects.

5.2.3.5. Summarize the IRB's consensus regarding any protocol specific findings justifying a determination.

5.2.3.6. Make a motion for one of the following actions:

5.2.3.6.1. *Approve*: Made when all criteria for approval are met.

5.2.3.6.1.1. Include in the motions for initial and continuing review a specific period of approval (continuing review interval) when applicable and the level of risk (minimal risk or greater than minimal risk). The period of approval cannot exceed one year for:

5.2.3.6.1.1.1. FDA regulated Research

5.2.3.6.1.1.2. Research subject to the Pre-2018 Common Rule.

5.2.3.6.1.1.3. Research where continuing review is not required in accordance with the 2018 Common Rule but the reviewer has determined otherwise.

5.2.3.6.1.2. State any new protocol specific findings that require documentation.

5.2.3.6.1.2.1. When reviewing modifications, determine if the changes might affect an ongoing participant's willingness to participate and require notification or re-consent.

5.2.3.6.2. *Require Modifications*: (Noted in Cayuse electronic system as: *Approval Pending Minor Stipulations)* Made when the initial, continuing, or modification submission will meet the criteria for approval with administrative, minor or prescriptive changes or requirements that can be verified by the IRB Chair and/or designated reviewer.

5.2.3.6.2.1. Responsive materials from the investigator are due 30 calendar days from IRB notification of determination.

5.2.3.6.2.2. If additional time is needed, the Investigator is to contact the IRB within 30 days.

5.2.3.6.3. *Disapproved:* Made when the research does not qualify for Approval or Modifications Required to Secure Approval and there are extensive deficiencies, or the IRB has no recommendations that might make the protocol approvable.

5.2.3.6.3.1. When making this motion, summarize the IRB's reasons for the decision and recommendations, if any.

5.2.3.6.4. *Suspension*: Based on new information, the previously approved research no longer meets the criteria for approval, but some research activities may meet the criteria for approval or the IRB has recommendations that may make the research meet the criteria for approval.

5.2.3.6.4.1. Include in the motion: Which research activities must stop or be modified.

5.2.3.6.4.2. If the research in its entirety no longer meets the regulatory criteria for approval, include in the motion: Stop all research procedures (except as noted below) and stop enrollment.

5.2.3.6.4.3. If stopping enrollment will adversely affect the best interests of currently enrolled subjects, include in the motion: Which subjects can continue and what procedures can be performed.

5.2.3.6.4.4. Lead the IRB members through a discussion to consider what additional actions are needed, if any.

5.2.3.6.4.5. Summarize the IRB's reasons and recommendations.

5.2.3.6.5. *Closed*: Based upon new information, the previously approved research no longer meets the criteria for approval and the IRB has no recommendation to make the research approvable.

5.2.3.6.5.1. Lead the IRB members through a discussion of additional actions to consider.

5.2.3.6.5.2. Summarize the IRB's reasons for the decision.

5.2.3.7. Open the floor for additional discussion.

5.2.3.8. Ensure that the required modifications include all final contingencies in the review activity, if any.

5.2.3.9. Call for a vote.

5.2.3.9.1. Only IRB members at the meeting may vote.

5.2.3.9.2. For a motion to be approved, it needs the approval of more than half of the members present at the meeting. Example: (If there are 10 or 11 members present at the meeting, 6 votes are required for approval, which is greater than 5 and 5.5, respectively.)

5.2.3.9.3. Record the vote by electronic polling when available or by voice or show of hands.

5.2.3.9.4. Ensure that the IRB staff taking minutes has recorded the IRB's actions, required modifications, reasons, recommendations, determinations, and findings.

5.2.3.10. Re-invite IRB members with a Conflicting Interest back into the meeting.

5.2.3.11. Adjourn the meeting when there is no further business or when notified by the research compliance staff assigned to the IRB that quorum has been lost and cannot be restored.

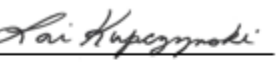
6. REFERENCES

6.1. 21 CFR §50.20, §50.25, §50.27, §56.109, §56.111

6.2. 21 CFR §56.108(c)

6.3. 45 CFR §46.108(b)

6.4. 45 CFR §46.109, §46.116, §46.117

Approved by: 

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