	SOP: IRB Convened Meeting Preparation	
TEXAS A&M UNIVERSITY KINGSVILLE	Section II: IRB Members and Meetings	
	Number	Effective Date
	IRB II-004	9/13/2025

1. PURPOSE

1.1. This SOP outlines the process to prepare for a convened IRB meeting.

1.2. The process begins when the meeting agenda is prepared.

1.3. The process concludes when the IRB members attending the meeting have been notified of the meeting agenda and their assignments.

2. REVISION FROM PREVIOUS VERSIONS

2.1. None

3. **SOP STATEMENT**

3.1. IRB members are provided sufficient information so that each member can provide an opinion on whether the regulatory criteria for approval of submissions are met.

3.2. 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.

3.3. 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.

3.4. The non-scientific member must be present in order for the meeting to take place. If the member for that board is unable to attend, then the alternate non-scientific member must be present in order for the meeting to proceed.

3.5. There must be half plus one board members present including the non-scientific 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.

3.6. Review materials are accessible to all IRB members in the Cayuse electronic system as they are placed on the agenda at least 5-7 days before convened meetings.

3.7. A new information item that requires immediate action to protect the rights and welfare of subjects may be placed on the next IRB agenda at any time prior to the meeting.

3.8. IRB members attending the meeting will be notified of any additional new information items added to the agenda.

4. RESPONSIBILITIES

4.1. Research compliance staff assigned to the IRB and members of the IRB carry out these procedures.

5. PROCEDURE

5.1. The IRB does not place limits on the number of items on the agenda.

5.2. An email will be sent out to let the board members know the date/time/details of the meeting.

5.3. Agendas are used to communicate to the IRB what will take place during the meetings.

5.4. Once a meeting and agenda is created in the Cayuse electronic system, the committee members will have access to all related submissions/documents/attachments through the Cayuse electronic system. This includes the following items if applicable:

- 5.4.1. Application form with local context and protocol procedures
- 5.4.2. Consent/Assent document(s) and script(s)
- 5.4.3. Investigators CITI training certificates
- 5.4.4. Recruitment materials
- 5.4.5. Survey instruments
- 5.4.6. Approval letters for other sites, if applicable
- 5.4.7. Any other material the IRB feels is needed to complete the review of the study.

5.5. The research compliance staff assigned to the IRB will confirm which IRB members (regular and/or alternate) will be present at the meeting.

5.6. All members will review all submissions placed on the agenda for a convened IRB meeting.

5.7. The research compliance staff assigned to the IRB prepares an agenda for the meeting with the following items (items 5.7.2, 5.7.3, 5.7.4, 5.7.5, are required for each meeting, but may be ordered per the Chair's preference):

- 5.7.1. Call to Order of meeting by the IRB Chair
- 5.7.2. Review of the Convened Protocols
- 5.7.3. Approval of the previous meeting minutes
- 5.7.4. Discussion of new business
- 5.7.5. Continued IRB Training
- 5.7.6. Acknowledgement of next scheduled meeting
- 5.7.7. Meeting Adjournment

5.8. The research compliance staff assigned to the IRB will, in consultation with the IRB Chair, assign a primary reviewer to each study listed on the agenda.

- 5.8.1. All scientific (member whose primary concerns are in scientific areas)/non-scientific (member whose primary concerns are in nonscientific areas) members are responsible for reviewing the study regardless primary reviewer status.

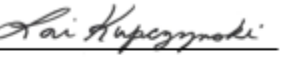
5.9. IRB Convened Board Protocol Checklist will be attached to the agenda in the Cayuse electronic system.

5.10. The research compliance staff assigned to the IRB will make arrangements with the PI of the study to ensure they are available during the meeting to present their study, if needed.

6. REFERENCES

6.1. 45 CFR §46.108(b)

6.2. 21 CFR §56.108(b)

Approved by: 

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Date: 8 September 2025