TEXAS A&M UNIVERSITY KINGSVILLE	SOP: Applications submitted to the IRB	
	Section III: IRB Protocols	
	Number	Date
	IRB III-003	9/13/2025

1. PURPOSE

1.1. This SOP outlines the triage process for applications submitted to the IRB.

1.2. The process begins when an application is received by the IRB through the Cayuse electronic system.

1.3. The process concludes when the research compliance staff assigned to the IRB determines the appropriate action for the received information.

2. REVISION FROM PREVIOUS VERSIONS

2.1. None

3. SOP STATEMENT

3.1. None

4. RESPONSIBILITIES

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

5. PROCEDURE

5.1. All IRB applications will come directly to the research compliance staff assigned to the IRB through the Cayuse electronic system.

5.1.1. Upon submission, the research compliance staff assigned to the IRB performs an initial assessment for technical issues, per SOP III-02.

5.2. For Initial Applications:

5.2.1. PI will initially identify review level in the application. The research compliance staff assigned to the IRB will confirm initial identification of review level or designate a different level of review. During the review process, an IRB member will make the final determination regarding the level of review required.

5.2.2. Once the pre-review is complete and any technical issues are resolved, the research compliance staff assigned to the IRB will assign the protocol to the next assigned reviewer through the Cayuse electronic system when it is expedited or exempt procedure 5.4 will be followed. Convened reviews will follow the procedures outlined in 5.8.

5.3. In cases where an IRB member determines that the initial review categorization is incorrect, the member will correctly categorize the level of review required and send it back to the research compliance staff assigned to the IRB for redirection to the appropriate procedural track.

5.4. Once the review is complete and required changes have been identified, the research compliance staff will return the protocol to the PI to implement the required changes.

5.4.1. If modifications are necessary, the research compliance coordinator assigned to the IRB will await the revised submission from the PI before forwarding it to the reviewer for review and approval.

5.4.2. Once approved, the research compliance staff assigned to the IRB will send the PI the approval letter for the study to commence. This will be sent electronically through the Cayuse electronic system.

5.5. For Renewals:

5.5.1. Once the renewal application and documents are reviewed for technical issues, the research compliance staff assigned to the IRB will send the application for review to the next assigned reviewer through the Cayuse electronic system.

5.5.2. Once approved, the research compliance staff assigned to the IRB will issue a new approval letter with the new expiration date. This will be sent through the Cayuse electronic system.

5.6. For Amendments:

5.6.1. In cases of exempt and expedited protocols, once the renewal application and documents are reviewed for technical issues, the research compliance staff assigned to the IRB will send the amendment to the original reviewer or Chair for review and approval. Research compliance staff assigned to the IRB will send modifications and amendments for convened studies to the Chair to be reviewed at a convened meeting in accordance with the procedure in 5.8.

5.6.2. If modifications are requested, the modifications will be emailed electronically through the Cayuse electronic system.

5.6.3. Once approved, the research compliance staff assigned to the IRB will issue an approval letter for the amendment. This will be sent through the Cayuse electronic system

5.7. Final Reports/Study Closure:

5.7.1. Once submitted by the PI, the research compliance staff assigned to the IRB will send the final report/study closure to the IRB chair for review and approval.

5.7.2. Once approved, the research compliance staff assigned to the IRB will close the study in Cayuse electronic system and an email notification will be sent to the PI.

5.8. For Convened Meetings:

5.8.1. To be considered for review at the monthly meeting, studies must be submitted by 5:00PM on the first business day of each month. If not submitted by this date and time, the IRB application will be tabled until the next scheduled meeting.

5.8.2. The day of the meeting, the investigators need to be available to attend the meeting to answer any questions the board members may have.

5.8.2.1. The research compliance staff assigned to the IRB will send the meeting link to the investigator(s) the day before the scheduled meeting or earlier.

5.8.2.2. The day of the meeting, the research compliance staff assigned to the IRB will contact the investigator(s) to let them know when to join the meeting. If the board members decide they don't need to speak with the investigators, the research compliance staff will let the investigator(s) know via email or text message.

5.8.3. After the meeting is conducted, the research compliance staff assigned to the IRB will email the investigator(s) with the meeting outcome.

5.8.3.1. If modifications are requested, the modifications will be emailed from the Cayuse electronic system.

5.8.3.2. Once approved, the research compliance staff assigned to the IRB will issue an approval letter to the PI. This will be sent electronically through the Cayuse electronic system.

5.8.4. Follow TAMUK SOP: IRB Convened Meeting Preparation (IRB SOP II-004).

6. **REFERENCES**

6.1. None

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