TEXAS A&M UNIVERSITY KINGSVILLE	**SOP: Exempt, Limited, and Expedited Reviews: Non-Committee Review Preparation and Review Conduct**	
	Section III: IRB Protocols	
	Number	Date
	IRB III-004	9/13/2025

1. PURPOSE

1.1. This SOP outlines the procedure for assigning a designated reviewer for a non-committee review. Non-committee reviews are those that are completed by individual members of the IRB or the Chair and may include consultants and do not require a convened review. Reviews follow the same procedure for exempt reviews, limited reviews, expedited reviews, and determinations of "not engaged in human subjects research".

1.2. The process begins when the designated reviewer is notified to conduct a non-committee review.

1.3. The process concludes when the designated reviewer notifies the research compliance staff assigned to the IRB of the completion of the review.

2. REVISION FROM PREVIOUS VERSIONS

2.1. None

3. SOP STATEMENT

3.1. Reviewers are expected to review, as applicable, the materials according to their role as described in TAMUK SOP: IRB Member Review Expectations (IRB SOP II-003).

3.1.1. The designated reviewer carries out the review of research that is eligible for exempt or expedited review.

3.2. The designated reviewer may not disapprove research. However, the designated reviewer can determine that a protocol should be a convened review in cases where convened review is necessary due to significant risks or other factors. The designated reviewer can also send the protocol back to the PI for requested/required revisions/modifications as described in 5.2.4 in this document.

4. RESPONSIBILITIES

4.1. The research compliance staff assigned to the IRB carries out the review preparation responsibilities.

4.2. The designated reviewer conducts the review procedures.

5. PROCEDURE

5.1. The research compliance staff assigned to the IRB will determine whether a protocol meets the criteria for non-committee review by reviewing the protocol and determining that it does not include vulnerable populations, and the PI has identified "minimal risks" in participating. If the research does not meet these criteria and requires review by a convened IRB, the research compliance staff assigned to the IRB will place the submission on the agenda for the next convened IRB meeting with the appropriate scope and follow TAMUK SOP: Convened Meeting Preparation (IRB SOP II-004). In all non-committee reviews, the designated reviewer makes the final determination of appropriate review level.

5.2. Review Preparation:

5.2.1. Refer to the IRB log for eligible designated reviewers.

5.2.2. Select the designated reviewer based on who is next in line to review from the IRB log.

5.2.3. Once the designated reviewer is selected, provide the study documents, initial application, and any other required documents to the designated reviewer via the Cayuse electronic system.

5.3. Review Conduct:

5.3.1. The designated reviewer fulfills the roles described for the primary reviewer as described in TAMUK SOP: IRB Member Review Expectations (IRB SOP II-003).

5.3.2. The designated reviewer reviews all materials within seven calendar days of submission.

5.3.3. If there is missing information:

5.3.3.1. Request Clarification from the investigator. The reviewer will do this by noting the missing information in the Cayuse electronic system review then submit the determination of "Return to PI"

5.3.3.2. The research compliance staff assigned to the IRB will return the application to the PI. TAMUK SOP: Repositories: Banking of Identifiable Specimens or Data (IRB SOP III-18) covers non-responses from the PI.

5.3.4. The designated reviewer may take one of the following actions to determine status of submission for protocols using the non-committee review process using the following guidance/decision tools:

Exempt
Exempt-Limited Review
Not Exempt
Minor Stipulations
Deferred
No engagement in Research
No Human Subjects Research
Rely on External IRB
Rely on NCI-CIRB
Return to PI
Voided

5.3.5. The designated reviewers may take one of the following actions to determine status of submission for Expedited protocols using the non-committee review process using the guidance/decision tools in 5.3.4:

Approved
Deferred
Exempt
Exempt-Limited IRB
Minor Stipulations
No engagement in Research
No Human Subjects Research
Not Expedited
Rely on External IRB

Rely on NCI-CIRB

Return to PI

Voided

5.3.6. Guidance/Decision tools used by designated reviewers:

5.3.6.1. Human Subjects Research: Decision Tool: Am I Doing Human Subjects Research: (https://grants.nih.gov/policy-and-compliance/policy-topics/human-subjects/hs-decision)

5.3.6.2. Exempt Review Charts: Human Subject Regulations Decision Charts: 2018 Requirements (multiple charts at this link): (https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html)

5.3.6.3. Expedited Review: use 45 CFR §46.110(b)

6. REFERENCES

6.1. 21 CFR §56.110(b).

6.2. 45 CFR §46.110(b).

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