	SOP: Member Review Expectations	
TEXAS A&M UNIVERSITY KINGSVILLE	Section II: IRB Members and Meetings	
	Number	Effective Date
	IRB II-003	9/13/2025

1. PURPOSE

1.1. This SOP outlines the review of Human Research the expectations of the IRB members and/or IRB team.

2. REVISION FROM PREVIOUS VERSIONS

2.1. None

3. SOP STATEMENT

3.1. In this SOP, "IRB Team" refers to all members of the committee and the research compliance staff assigned to the IRB.

3.2. The designated reviewer is considered an experienced member of the IRB by the IRB chair if they have demonstrated sufficient experience in and knowledge of conducting IRB reviews.

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

3.4. All members of the IRB team are to treat all oral, written, and electronic information obtained as part of the review process as confidential. IRB members must not disclose, use, share or duplicate review documents or confidential information without prior authorization.

3.5. All members of the IRB team are to know the definition of Conflict of Interest.

3.5.1. No IRB member may participate in any review in which he or she has a Conflict of Interest, except to provide information requested by the IRB.

3.5.2. When reviewing an item, each IRB member is to consider whether he or she has a Conflict of Interest, and if so, to disclose that Conflict of Interest and recuse him or herself from participation.

4. RESPONSIBILITIES

4.1. The IRB Chair, IRB members and/or team, and research compliance staff assigned to the IRB are responsible for carrying out these procedures.

5. PROCEDURE

5.1. All IRB members are provided a user account in the Cayuse electronic system to access review materials.

5.1.1. All IRB members are to access review materials through the electronic system.

5.2. When applications come into the electronic system, the research compliance staff assigned to the IRB will pre-screen for technical issues and then assign the protocol to a designated reviewer.

5.3. Exempt/Expedited Reviews:

5.3.1. Exempt and Expedited reviews are conducted on a rolling basis.

5.3.2. Exempt applications can be reviewed by the IRB Chair, IRB member, or member of the IRB team designated by the Chair.

5.3.3. Once the pre-review has been completed, the application will be assigned to a designated reviewer for review by research compliance staff assigned to the IRB.

5.3.4. The designated reviewer makes a determination and sends their review back to the research compliance staff assigned to the IRB through the Cayuse electronic system.

5.4. Convened Reviews:

5.4.1. All members assigned as a primary reviewer, or scientific/scholarly reviewers, are to consider whether they have sufficient expertise to review the submission. If additional expertise is required, follow TAMUK SOP: Consultation (IRB SOP III-007). Sufficient Expertise includes as applicable for the research:

5.4.1.1. Scientific or scholarly expertise

5.4.1.2. Knowledge of or experience working with vulnerable populations

5.4.1.3. Qualifications as a prisoner representative

5.4.1.4. Knowledge of the country in which the research is conducted

5.4.1.5. Medical licensure for FDA-regulated test articles

5.4.1.6. Knowledge of community base participatory research

5.5. The convened meetings will have a primary reviewer for each submission, but all IRB members will have access to review all documents for each submission prior to the meeting.

5.5.1. IRB members consider the applicable criteria for each submission and discuss them with each other at the convened meeting.

5.5.2. The primary presenter for each submission summarizes their review and presents preliminary judgments as to whether each criterion is met along with the rationale for the determination.

5.5.3. Once the primary reviewer presents their findings, then the additional IRB members may ask any questions they have.

5.5.4. When all discussions are complete, the IRB Chair will call for a motion and a second.

5.5.5. The chair will ask the committee members to approve, disprove, or abstain. The outcome will be recorded in the IRB meeting minutes.

5.6. Conflict of Interest:

5.6.1. Before reviewing research, IRB members are to determine whether they have a Conflict of Interest with the research, and if so, recuse themselves from participating in that review.

5.6.2. If an IRB member has a Conflict of Interest in connection with a review outside a meeting (e.g., the exempt or expedited procedure), he or she is to notify the research compliance staff assigned to the IRB so the submission can be re-assigned.

5.6.3. If an IRB member has a Conflict of Interest in connection with a review of a submission for which he or she has been assigned as a primary reviewer at the meeting, he or she is to notify the research compliance staff assigned to the IRB so the submission can be re-assigned.

5.6.4. If an IRB member has a Conflict of Interest in connection with a review of research at a meeting, he or she is to notify the meeting chair, stay in the meeting only to answer questions about the research where requested, or leave the meeting for discussion and voting regarding that research.

5.6.5. The research compliance staff assigned to the IRB will record in the meeting minutes the name of the IRB member leaving the meeting because of a Conflict of Interest.

5.6.6. The IRB member with a Conflict of Interest will not count towards quorum for that specific research.

6. REFERENCES

6.1. 21 CFR §56.104

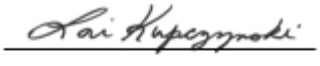
6.2. 21 CFR §56.107(e)

6.3. 21 CFR §56.110(b)

6.4. 45 CFR §46.104

6.5. 45 CFR §46.107(e)

6.6. 45 CFR §46.110(b)

Approved by: 

Lori Kupczynski, EdD
Special Assistant to the Vice President,
Office of Research and Innovation

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