TEXAS A&M UNIVERSITY KINGSVILLE	**SOP: Institutional Official, Membership Management, and Responsibilities of the IRB**	
	Section I: Administrative Management	
	Number	Effective Date
	IRB I-002	9/13/2025

1. **PURPOSE**

1.1. This SOP describes Texas A&M University-Kingsville's Institutional Official, membership management, and the responsibilities related to the operation of the TAMUK IRB.

2. REVISION FROM PREVIOUS VERSIONS

2.1. None

3. SOP STATEMENT

3.1. The Institutional Official (IO) is the individual authorized to act for the university and to assume on behalf of the University the obligations imposed by federal law and regulations.

3.2. The IO may delegate these authorities as appropriate to other experienced individuals in the IRB but may not delegate institutional authority for the IO role.

3.3. Members of the IRB provide an invaluable service to the TAMUK research community and to the volunteer participants in TAMUK research. IRB members have an obligation to maintain the highest standards of judgement relative to their duties as members. This document provides an overview of IRB members and research compliance staff standards and responsibilities.

4. RESPONSIBILITIES

4.1. The Institutional Official, IRB Chair, research compliance staff assigned to the IRB, or designee are responsible for carrying out these procedures.

5. PROCEDURE

5.1. The Institutional Official (IO) assumes the following responsibilities:

5.1.1. The IO is legally authorized to represent the institution for matters related to research conducted under the auspices of TAMUK, is the signatory official for all Assurances, and assumes the obligations of the Institution's Assurance. The IO may authorize a designee in writing for specific responsibilities/tasks to be carried out by alternate knowledgeable officials of the institution.

5.1.2. Provides oversight for research conducted under the auspices of TAMUK.

5.1.3. Provides oversight and support for the TAMUK Institutional Review Board.

5.1.4. Ensures that the IRB operates fairly and impartially and is immune to pressure by the institution's administration, PIs, and other professional and non-professional sources.

5.1.5. Appoints a Chair for the IRB.

5.1.6. Reviews the performance of the TAMUK IRB Chair on an annual basis and provides feedback as appropriate.

5.1.7. Removes the Chair for reasons including (but not limited to) the following: if the Chair is not acting in accordance with the IRB's mission, is not following policies and procedures, has an excessive number of absences, or is not fulfilling the responsibilities of the Chair.

5.1.8. Appoints members (other than Chair and Vice Chair) to the Institutional Review Board to serve for renewable three-year terms in consultation with the TAMUK IRB Chair.

5.1.9. The IO shall not approve research that has been disapproved or not yet approved by the IRB.

5.2. The research compliance staff assigned to the IRB assumes the following responsibilities:

5.2.1. Registration and Assurances

5.2.1.1. Maintains registration for the TAMUK IRB with the Department of Health and Human Services.

5.2.1.2. Updates the IRB Registration information within 90 days when the following changes occur.

5.2.1.2.1. Contact person who provided the IRB registration information changes.

5.2.1.2.2. The IRB Chair, membership, or contact information changes.

5.2.1.3. Submits, implements, and maintains an approved Federal Wide Assurance (FWA) under the direction of the IO and through the Department of Health and Human Services Office of Human Research Protection (OHRP).

5.2.1.4. Communicates change in appointment of all IRB members and/or IRB Chair to the research community by making the roster available on the relevant website, shared location or upon request.

5.2.1.5. Serves as the primary contact for the TAMUK Office for Human Research Protections (OHRP) of the U.S. Department of Health and Human Services and other federal regulatory agencies.

5.2.2. TAMUK IRB Oversight/Membership Management

5.2.2.1. Actively makes recommendations regarding the membership roster to ensure the membership is adequate for the volume and type of research, based on metrics and other evaluation strategies, under the direction of the IRB Chair.

5.2.2.2. Creates and updates written procedures for assigning appropriate IRB reviewers to ensure that the reviews are completed by individuals with appropriate scientific or scholarly expertise and other expertise or knowledge as required, under the direction of the IRB Chair and the IO.

5.2.2.3. Provides written feedback regarding IRB member performance to the Chair, upon request and/or no less than semi-annually, including metrics of number of reviews performed.

5.2.2.4. Ensures the development and implementation of an educational plan for IRB members, staff, and researchers to verify that IRB members are appropriately knowledgeable to review research per ethical standards and applicable regulations, including ensuring CITI and other IRB training is completed and updated.

5.2.2.5. Follows institutional and federal policy related to competing business interests and Conflict of Interest.

5.2.2.6. Ensures the availability of alternates to take a member's place in the event of unavailability or a prolonged absence.

5.2.2.7. Manages relevant updates when there are changes in appointment of membership and chairs (including reappointment or removal), including but not limited to roster updates, updating FWA, adding or removing members from listservs, and ensuring the appropriate training and onboarding events have taken place.

5.2.3. TAMUK IRB Other Duties

5.2.3.1. Serves as the initial contact to the research community for all IRB communications.

5.2.3.2. Facilitates the review of a protocol through the Cayuse electronic system.

5.2.3.3. Facilitates the training for IRB members, IRB alternates, PIs, faculty, staff, and students on the ethical conduct of research involving human subjects.

5.2.3.4. Updates IRB website.

5.2.3.5. Prepares the meeting agendas and documents and update the meeting records.

5.2.3.6. Maintain records of the IRB proceedings and decisions.

5.2.3.7. Assure the IRB records are being maintained appropriately and that records are accessible upon request to authorized federal officials.

5.2.3.8. Maintains and update membership rosters as needed.

5.2.3.9. Other duties as assigned.

5.3. The IRB Chair assumes the following responsibilities:

5.3.1. Ensure that the actions of the IRB are fair, impartial, and immune to pressure by the institution's administration, the PIs, and other professional and non-professional sources.

5.3.2. Designate other members to perform duties, as appropriate, for review, signature authority, and other IRB functions (e.g., the Vice Chair).

5.3.3. Conduct member evaluations and advises the IO regarding member performance and competence.

5.3.4. Solicit individuals from the organization or the community with competence in special areas to assist in reviewing issues or protocols, which require appropriate scientific or scholarly expertise beyond or in addition to the current membership.

5.3.5. Attends required training and presentations related to policy and regulatory changes.

5.3.6. Follows institutional and federal policy related to competing business interests and Conflicts of Interest.

5.3.7. Maintains the security and confidentiality of research information (proposals, protocols, support data) according to regulatory and institutional policies.

5.4. The IRB Vice Chair assumes the following responsibilities:

5.4.1. The Vice Chair serves as the Chair of the IRB in the Chair's absence and has the same qualifications, authority, and duties as the Chair.

5.5. The IRB members assume the following responsibilities:

5.5.1. Attend the scheduled IRB meetings to contribute to quorum, and to vote to approve, require modifications, or disapprove human research protocols. If a member cannot attend a scheduled meeting, the IRB Chair and designated TAMUK research compliance staff assigned to the IRB

should be informed at least five days before the planned meeting (except in cases of emergency outside of the IRB member's control).

5.5.2. Notify the IRB Chair at least 30 days in advance for planned absences for extended periods, such as a sabbatical (except in cases of emergency outside of the IRB member's control).

5.5.3. Review the materials at least one week before the meeting to facilitate full participation in the review (meeting materials are located in the Cayuse electronic system database).

5.5.4. Attend required training and presentations related to policy, procedure, and regulatory changes.

5.5.5. Follow institutional and federal policy related to competing business interests and Conflicts of Interest.

5.5.6. Maintain the security and confidentiality of research information (proposals, protocols, support data) according to regulatory and institutional policies.

5.5.7. Review (if needed) multiple protocols or other research items that require primary review.

5.6. The Alternate Member assumes the following responsibilities:

5.6.1. The appointment and function of alternate members are the same as those for primary members.

5.6.2. The expertise and perspective of the alternate member should be comparable to that of the primary member.

5.6.3. The alternate member's role is to serve as a voting member of the IRB when a primary member is unavailable to attend a convened meeting.

5.6.4. The alternate member will receive and review the same materials before the IRB meeting.

5.6.5. The roster identifies the primary member(s)' qualifications for whom each alternate member with comparable qualifications may substitute.

5.6.6. The alternate member will not be counted as a voting member unless the primary member is absent. The minutes will document when an alternate member replaces a primary member.

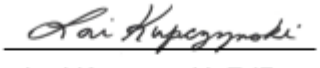
5.6.7. Alternate members can be temporary, for the period of absence, or permanent if an IRB member is not returning to the IRB.

5.6.8. Maintain the security and confidentiality of research information (proposals, protocols, support data) according to regulatory and institutional policies.

5.6.9. Review (if needed) multiple protocols or other research items that require primary review.

6. REFERENCES

6.1. 45 CFR 46.103

Approved by: 

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