

SOP: IRB Membership	
Section II: IRB Members and Meetings	
Number	Effective Date
IRB II-002	9/13/2025

## 1. PURPOSE

1.1. The purpose of this SOP is to outline the membership of the Texas A&M University-Kingsville Institutional Review Board (IRB).

## 2. REVISION FROM PREVIOUS VERSIONS

**2.1.** None

### 3. STATEMENT

- 3.1. The IRB members' primary duty is the protection of the rights and welfare of the individual human beings or their biospecimens who are serving as the subjects of research.
- 3.2. The IRB members are expected to be versed in regulations governing human subject protection, biomedical and behavioral research ethics, and the policies of Texas A&M University-Kingsville germane to human subject protection.

## 4. RESPONSIBILITIES

- 4.1. The Institutional Official appoints the IRB Chair.
- 4.2. The IRB Chair or designee appoints IRB members and alternate members.

### 5. PROCEDURE

- 5.1. IRB Membership:
  - 5.1.1. A minimum of at least five members;
  - 5.1.2. IRB members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.
  - 5.1.3. IRB members shall be sufficiently qualified through the varied experiences and expertise of members to promote sensitivity to the issues encountered by the IRB, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects, and to meet regulatory requirements to constitute an IRB.
  - 5.1.4. IRB members will include persons able to ascertain the acceptability of proposed human research activities in terms of institutional commitments, regulations, applicable law, and standards of professional conduct and practice;
  - 5.1.5. IRB members will consist of members from a variety of professions;
  - 5.1.6. The IRB will have at least one member whose primary expertise is in a scientific area and at least one member whose primary expertise is in a non-scientific area;
  - 5.1.7. The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution;
  - 5.1.8. No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, as described in TAMUK SOP: Member Review Expectations (IRB SOP II-003);

- 5.1.9. The composition of the IRB will contain at least one member who is knowledgeable about or is experienced in working with vulnerable populations when research involving participants vulnerable to coercion or undue influence is being reviewed;
- 5.1.10. The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

# 5.2. Board Members Responsibilities:

- 5.2.1. Board members must obtain and maintain current human subject's protection training, as outlined in TAMUK SOP: Member Education (IRB SOP II-008).
- 5.2.2. Board members will attend meeting regularly and complete reviews in advance to contribute effectively to discussions.
- 5.2.3. Board members will not allow their own interests or those of their department to supersede their duty to protect the rights and welfare of the research subjects.
- 5.2.4. Board members will communicate with the research compliance staff assigned to the IRB if they are unable to complete reviews, have conflicts of interest, or cannot attend a meeting. Board members should communicate with the research compliance staff assigned to the IRB if they require additional information or guidance.
- 5.2.5. If a board member cannot attend the meeting, an alternate member will be notified to attend in their place. However, the alternate member should have the same designation as the member for whom they are serving as an alternate member (e.g., scientist, non-scientist, community member, etc.).
  - 5.2.5.1. Their area of expertise as the alternate should match that of the regular member they are alternating for.
  - 5.2.5.2. The role of the alternate member is to serve as a voting member of the IRB when the regular member is unavailable to attend a convened meeting.
  - 5.2.5.3. IRB Alternate Members have the same authority, responsibilities, and duties as a regular member.
  - 5.2.5.4. Alternate members may be qualified to replace more than one regular member; however, only one such member may be represented by the alternate at any convened meeting.
  - 5.2.5.5. The IRB roster identifies the primary member(s) for whom each alternate member may substitute. This will also need to be listed on the OHRP website.
  - 5.2.5.6. The alternate member will not be counted as a voting member unless the primary member is absent.
  - 5.2.5.7. The IRB minutes will document when an alternate member replaces a primary member.

## 5.3. IRB Chair Responsibilities:

- 5.3.1. In addition to the above responsibilities as a member, the Chair moderates convened meetings.
- 5.3.2. The Chair should have previous experience serving on an IRB committee.
- 5.3.3. The Chair may delegate his/her responsibilities as appropriate to other qualified individual(s).

- 5.3.4. The Chair can suspend human subjects research when deemed necessary to protect the rights and welfare of participants, as noted in TAMUK SOP: Investigations, Suspensions Termination by the Institution (IRB SOP IV-007).
- 5.3.5. The Chair may recommend an IRB member who is not adequately fulfilling the responsibilities to the IO for additional training or for termination from the IRB.

### 5.4. IRB Member Addition:

- 5.4.1. Determine from the IRB Chair or designee whether the individual will be a regular IRB member or alternate IRB member.
- 5.4.2. Add the individual to the IRB Roster.
- 5.4.3. Provide the individual with the required CITI training instructions.
- 5.4.4. When the new IRB member has completed training:
- 5.4.5. Assign individual the appropriate role within the Cayuse electronic system.
- 5.4.6. Update the registration of the IRB at http://ohrp.cit.nih.gov/efile/ within 90 days.

## 5.5. IRB Member Removal:

- 5.5.1.Remove the individual from IRB Roster. Make sure the IRB is appropriately constituted.
- 5.5.2. Revise membership as needed.
- 5.5.3. Notify the IRB member.
- 5.5.4. Update the IRB at http://ohrp.cit.nih.gov/efile/ within 90 days.
- 5.5.5.File:
  - 5.5.5.1. IRB Roster
  - 5.5.5.2. Correspondence notifying IRB member of removal.
  - 5.5.5.3. Remove individual's IRB Committee Reviewer role in the Cayuse electronic system.

# 6. REFERENCES

6.1. 45 CFR §46.107

6.2. 21 CFR §56.107

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