TEXAS A&M UNIVERSITY
SAN ANTONIO

INSTITUTIONAL REVIEW BOARD (IRB) STANDARD OPERATING PROCEDURE (SOP)

SOP #: 2	**Version:** 2.0	**Effective Date:** June 27, 2024
Title: Membership and Responsibilities		
Approved by: Dr. Vijay Golla, PhD Vice Provost for Research and Health Sciences		**Date:** June 27, 2024

1. Purpose

1.1 This SOP outlines the roles and responsibilities of IRB members at Texas A&M University-San Antonio (A&M-SA).

2. Scope

2.1 Federal requirements, system and university guidelines and policies are formed in line with 45 CFR 46.107 and enforced for the ultimate purpose of human subjects' protection.

3. Procedures

3.1 IRB Membership

3.1.1 The IRB will consist of at least five members, with varying backgrounds to promote complete and adequate review of research activities conducted by the institution.

3.1.2 The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

3.1.3 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.

3.1.4 The IRB shall include at least one member who primarily represents the perspective of the research participants.

3.2 Term of Service

3.2.1 Members will be appointed to the committee by the Institutional Official (IO) for a period of three years (calendar year).

3.2.2 Attendance is required remotely via video or call, and members are expected to attend at least 75% of convened meetings.

3.2.3 Performance evaluations may be conducted at the discretion of the IRB Chair.

4. Appointments

4.1. Appointing a Chair

4.1.1 The IO will appoint the IRB Chair for a term of no less than three years, with a

maximum of two terms unless reappointed by the IO.

4.1.2 The Chair should have previous experience serving on an IRB committee.

4.1.1 The Research Compliance Administrator (RCA) will draft the IRB Chair Appointment Letter to be signed by the IO.

4.1.2 The RCA will send the IRB Chair Appointment Letter to the Chair and retain records of membership period and training.

4.2. Appointing a Vice Chair

4.2.1 The IO will appoint the Vice-Chair for a term of no less than three years.

4.2.2 The Vice Chair should have previous experience serving on an IRB committee.

4.2.3 If the Chair position is vacant, the Vice Chair may assume the role of interim Chair until such time that the IO appoints a new Chair.

4.1.3 The Research Compliance Administrator (RCA) will draft the IRB Vice Chair Appointment Letter to be signed by the IO.

4.1.4 The RCA will send the IRB Vice Chair Appointment Letter to the Vice Chair and retain records of membership period and training.

4.3. Appointing Full Members

4.3.1 If a position is vacant or soon-to-be vacant, the IO will consult with the Chair and fill the vacancy.

4.3.2 Prospective members will be invited attendees to three convened meetings before they may be selected to serve on the committee.

4.3.3 The IO will appoint the Full Member for a term of no less than three years.

4.3.4 Upon completion of a committee member's three-year term, the IO may choose to renew their membership or appoint a new member in their place.

4.3.5 The Research Compliance Administrator (RCA) will draft the IRB Membership Appointment Letter to be signed by the IO.

4.3.6 The RCA will send the IRB Membership Appointment Letter to the Full member and retain records of membership period and training.

4.4. Appointing Alternate Members

4.4.1 The IO will appoint Alternate Members as needed for a term of no less than three years.

4.4.2 Upon completion of a three-year term, the IO may choose to renew their membership or appoint a new member in their place.

4.4.3 The Research Compliance Administrator (RCA) will draft the IRB Alternate Membership Appointment Letter to be signed by the IO.

4.4.4 The RCA will send the IRB Alternate Membership Appointment Letter to the Alternate member and retain records of membership period and training.

4.5 Appointing Community Members

4.5.1 The IO will appoint the Community Member for a term of no less than three years.

4.5.2 Upon completion of the Community Member's three-year term, the IO may choose to renew their membership or appoint a new member in their place.

4.5.3 The Research Compliance Administrator (RCA) will draft the IRB Community Membership Appointment Letter to be signed by the IO.

4.5.4 The RCA will send the IRB Community Membership Appointment Letter to the Community Member and retain records of membership period and training.

5. Training

5.1 IRB Membership Training

5.1.1 The Chair, Vice Chair, Full, Alternate and Community Members should have relevant required CITI training completed with a minimum score of 80%.

- All members must submit documentation of CITI training to IRB@tamusa.edu upon appointment.
- CITI training expires after three years; members are responsible for maintaining current completion reports on file with the IRB Office.

5.1.2 All members must attend IRB Orientation provided by IRB leadership.

5.1.3 All members must attend at least one in-person IRB Annual Training provided by IRB leadership and staff.

6. Duties and Responsibilities

6.1. All Members

6.1.1 The task of making the IRB a respected part of the institutional community will fall primarily on the IRB members. IRB members must maintain the IRB's reputation for being fair and impartial, as well as invulnerable to pressure from the institution's administration, faculty, study investigators, or any other professional and nonprofessional sources.

6.1.2 Community Members are expected to provide input regarding their knowledge about the local community and be willing to discuss issues and research from that perspective.

6.1.3 Nonscientific members are expected to provide input on areas germane to their knowledge, expertise, and experience, professional and otherwise. Nonscientific members should advise the IRB if additional expertise in a nonscientific area is required to assess if the research proposal adequately protects the rights and welfare of subjects.

6.1.4 Scientific members are expected to contribute to the evaluation of a study on its scientific and statistical merits and standards of practice. Additionally, these members may also advise the IRB in a nonscientific area to assess if the research proposal adequately protects the rights and welfare of subjects.

6.1.5 The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues requiring expertise beyond or in addition to that available to the IRB. These individuals may not vote with the IRB.

6.2. IRB Chair

6.2.1 In addition to the above responsibilities, the IRB Chair conducts the convened meetings.

6.2.2 The Chair may delegate his/her responsibilities as appropriate to other qualified individual(s).

6.3. Vice Chair

6.3.1 The Vice Chair may assist or act on behalf of the IRB Chair on specific IRB matters and at convened meetings, either as a general procedure, or on a case-by-case basis.

6.4. Full Members

6.4.1 Full Members must contact the RCA in the event that they cannot attend a convened meeting.

6.4.2 The RCA will coordinate the participation of an Alternate Member.

6.5. Alternate Members

6.5.1 Alternate Members will serve in place of Full Members when they are unavailable.

6.6. Community Members

6.6.1 Community Members must contact the RCA in the event they cannot attend the convened meeting.

7. IRB Convened Meetings

7.1 Remote Participation

7.1.1 Convened meetings occur remotely. The meeting can be convened via phone or video call. The members must be able to hear the discussion and be heard by the convened members. Members participating by phone or video call may vote. Remote participation needs to be held in private to maintain confidentiality throughout the convened meeting.

7.1.2 A quorum must participate in the meeting to be convened. To allow for appropriate discussion, all members must be connected simultaneously for a remote convened meeting to take place. All members must be able to hear one another to allow for discussion. Members that are not in attendance at the convened meeting, nor participating in the convened meeting may not vote on an agenda item or issue

discussed during a convened meeting (voting by proxy is not permitted).

8. IRB Confidentiality Agreement

8.1.1 All materials received by the IRB will be considered confidential and will be distributed only to convened meeting participants (e.g., Full, Alternate and Community Members, and ad hoc consultant reviewers) for the purpose of review.

8.1.2 All participants, including ad hoc consultants and visitors, will be expected to sign the IRB Confidentiality Agreement and Conflict of Interest Declaration Form. Printed copies of applicable documents will be available as necessary.

8.1.3 At the end of the meeting, all documents shared with the consultants and visitors will be retrieved.

9. IRB Review

9.1 Initial Review

9.1.1 After an Administrative Pre-Review, the IRB Chair or designee shall make an initial determination of all incoming protocols.

9.1.2 If the IRB Chair or designee makes the determination that the protocol is Expedited, the RCA will select a primary and secondary reviewer from the member pool. The selection will be based on the relevant expertise, potential conflicts of interest, and availability of the members. Whenever possible, at least one reviewer will have scientific and scholarly experience similar to the project under review. Anonymity of primary and secondary reviewers must be maintained.

9.2 Primary Reviewer

9.2.1 The Primary Reviewer is responsible for generating comments about the protocol and sending comments to the RCA.

9.3 Secondary Reviewer

9.3.1 The Secondary Reviewer is responsible for generating comments about the protocol and sending comments to the RCA.

9.4 The RCA is responsible for compiling comments from both the Primary and Secondary Reviewers as correspondence to the PI, corresponding with IRB Chair or designee in the event of disagreement between the Primary and Secondary Reviewer, sending the correspondence to the PI, and performing any subsequent reviews after revisions from the PI.

9.5 If the protocol is to be discussed at a convened meeting, the Primary Reviewer and Secondary Reviewer are expected to review the materials in sufficient depth to be familiar with and prepared to discuss the information.

9.6 Ad Hoc Reviewer

9.6.1 Under conditions where the IRB Chair or designee determines that the committee does not possess sufficient expertise to review all aspects of a protocol under consideration, the IRB Chair or designee will coordinate with the RCA to identify an appropriate consultant. This consultant could be either affiliated or un-affiliated with A&M-SA but must not have any conflicts of interest that would preclude unbiased review.

9.6.1.2 The reviewer will serve as an additional reviewer, not replacing but adding to what committee members already identify. They will work with the IRB Chair, who will assume the role of the Primary Reviewer.

9.6.2 All members of the IRB have access to the submitted documents and may provide comments regarding any proposed research. Any member, at their discretion, can request an ad hoc review.

10. References

10.1 Texas A&M University. Institutional Review Board. Standard Operating Procedures. SOP: Member Review Expectations. Retrieved August 4, 2020 from: https://rcb.tamu.edu/humansubjects/forms/standard-operating-procedures-sops

10.2 The University of Utah, Institutional Review Board. Standard Operating Procedures. Retrieved June 11, 2020, from: https://irb.utah.edu/guidelines/irb-sops.php

10.3 UC Davis Office of Research. Institutional Review Board Standard Operating Procedures. Retrieved June 11, 2020, from: https://research.ucdavis.edu/policiescompliance/irb- admin/policies-procedures-regulations/irbsops/#Review%20Process

10.4 Mercy Health. Institutional Review Board Policies. Retrieved June 11, 2020, from: https://www.mercyhealth.com/research-and- innovation/institutional-review-board/irb-standardoperating-procedures

11. Revision History

11.1 June 2022, June 2024