SOP #: 2	Version: 2.0
Title: Membership and Responsibilities	
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1. Purpose

The purpose of this SOP is to outline roles and responsibilities of IRB members and the review of Human Subjects in Research at Texas A&M University – San Antonio (A&M-SA).

2. Scope

Federal, System and University policy are all formed and enforced for the ultimate purpose of human subjects' protection. IRB members are subject to 45 CFR Part 46 Subpart A.

3. Composition

3.1 IRB Membership

3.1.1 The IRB shall 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 (as defined in the Definitions SOP).

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 (as defined in the Definitions SOP).

3.2 Terms 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 If unable to attend in person, attendance is required virtually via video or call in, but 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.

4.2. Appointing a Vice-Chair

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

4.2.2 The Vice-Chair should have previous experience serving on an IRB committee, at the university or elsewhere.

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

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 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 of cumulative service to the committee (including any service as an alternate member).

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 DRC will draft the IRB Membership Appointment Letter to be signed by the IO.

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

4.4. Appointing an Alternate Member

4.4.1 The IO will appoint alternate members as needed for a term of no less than three years of cumulative service to the committee (including any service as a full member).

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 DRC will draft the IRB Alternate Membership Appointment Letter to be signed by the IO.

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

4.5 Break in Service

4.5.1 Whenever possible, notification must be sent to the IRB Chair and the Research Compliance Administrator 30 days in advance of a break in service (e.g., authorized leave of absence or sabbatical) so that an alternate member may be appointed as temporary replacement.

5. Training

5.1 IRB Membership and CITI Training

5.1.1 The Chair, Vice-Chair, members including alternates and unaffiliated members should have relevant training including, but not limited to, IRB Membership, Responsible Conduct in Research, and Revised Common Rule CITI training. Members must attend orientation (typically in person) provided by ORC and IRB leadership. They should also complete an external workshops as recommended.

5.1.2 All members must submit documentation of current training to IRB@tamusa.edu upon appointment. Updated documentation should be sent to Research Compliance Administrator prior to expiration and at the request of the DRC and IO.

5.1.3 CITI training expires after three years; members are responsible for maintaining current completion reports on file within the IRB Office.

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 Unaffiliated 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 on the IRB. These individuals may not vote with the IRB.

6.2. Chair

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

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 in particular IRB matters and at IRB meetings, either as a general procedure, or a case-by-case basis.

6.4. Full Members

6.4.1 Full members must contact the Research Compliance Administrator in the event that they cannot attend a convened meeting.

6.4.2 The Research Compliance Administrator 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.

7. Convened IRB Meetings

7.1 Remote Participation

7.1.1 Should a member not be able to be physically present during a convened meeting, but is available remotely, the meeting can be convened using a speakerphone or video call. The member who is not physically present will be connected to the rest of the members via conferencing technology. The member must be able to hear the discussion and be heard by the convened members. In this manner, all members will be able to discuss the protocol even though one member is not physically present. Members participating by speakerphone or video call may vote, provided they have had an opportunity to review all the material the other members have reviewed. Such virtual participation needs to be held in private so that confidentiality is maintained throughout the meeting.

7.1.2 On occasion, meetings may be convened via telephone or video call conferencing. A quorum (as defined in the Definitions SOP) must participate for the conference call meeting to be convened. To allow for appropriate discussion, all members must be connected simultaneously for a conference call to take place. All members must be able to hear one another to allow for discussion. Members not present at the convened meeting, nor participating in the conference call may not vote on an 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 meeting participants (e.g., Full members, Alternate 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 and destroyed.

9. IRB Review

9.1 Initial Review

9.1.1 After a full and complete 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 Research Compliance Administrator will select a primary and secondary reviewer from a reviewer pool created by the IRB Chair or designee. 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 completing the IRB Reviewer Checklist, generating comments about the protocol, 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 Research Compliance Administrator to send to the PI, and performing any subsequent reviews after revisions from the PI.

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

9.3 Secondary Reviewer

9.3.1 The Secondary Reviewer is responsible for completing the IRB Reviewer Checklist, generating comments about the protocol, sending comments and IRB Reviewer Checklist to the Primary Reviewer, and following up with the Primary Reviewer as necessary.

9.4 Ad Hoc Reviewer

9.4.1 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 Research Compliance Administrator 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.

9.4.1.2 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 would assume the role of the Primary Reviewer.

9.4.2 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.

Revision history

Revised Version 06.8.22 RM

References:

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