



1.6.6 Institutional Review Board

Chapter 1 - Administration and Organization	Original Effective Date: June 2000
Section: 1.6 Administrative Committees	Date Last Reviewed: June 2021
Responsible Entity: Vice President for Research	Date Last Revised: June 2021

I. Purpose

The purpose of this Policy is to define membership terms, conditions, leadership selection and charge of the Institutional Review Board at the University of Texas Health Science Center at San Antonio (UT Health San Antonio). The President on behalf of the University grants the authority of the IRB as established by federal regulations (e.g., 45 CFR 46 and 21 CFR 50 and 56).

II. Scope

This Policy applies institution-wide to all non-exempt human research activities for UT Health San Antonio (University) faculty, staff, and/or students, considering to be engaged in research, in concordance with Office of Human Research Protections (OHRP) "Guidance on Engagement of Institutions in Human Subjects Research". The IRB has authority regardless of the location of the activity (e.g., University research activities outside the United States) or source of funding and includes as applicable any affiliated institution under an active IRB Authorization Agreement Form.

III. Policy

The UT Health San Antonio Institutional Review Boards (IRB or Board) are a component of the University's Human Research Protection Program (HRPP) and have authority over all human research activities approved by the IRB.

A. Charge

1. To ensure that the rights and welfare of research subjects are adequately protected and all activities involving human subjects are in compliance with University policies, and federal and state regulations. Protections of human subjects are provided by prospective and continuing review and approval of the scientific and ethical issues related to research under the University's HRPP. See Handbook of Operating Policies (HOP), [7.2.2 Institutional Review Board Responsibilities](#), which further specifies the accountabilities of the IRB.

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B. Membership

1. Each University Institutional Review Board (IRB or Board) consists of a Chair, and at least five (5) primary members. The Director of Research Regulatory Programs (RRP) determines the actual number and composition of Board members after taking into consideration the nature and volume of research reviewed.
2. One primary member is assigned to a Board and one or more formally appointed alternates are assigned based on diverse professional, ethnic/racial, gender, scientific and institutional affiliation backgrounds required by the federal regulations and appropriate to the research routinely reviewed. Board members may be assigned to more than one Board; however, no member is permitted more than one vote at any meeting.
3. Alternates attend meetings in the primary's absence and shall have similar expertise and qualifications. Members shall be drawn from the various components of the University, from other institutions that rely on the IRB and from the community-at-large to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
4. Each designated IRB will have members representing:
 - a. multiple scientific professions or backgrounds;
 - b. non-scientific professions or backgrounds;
 - c. various racial/ethnic backgrounds;
 - d. both genders; and,
 - e. various cultural backgrounds.
5. Each designated IRB will have at least:
 - a. one member with no affiliation with the University or other institutions that utilize the University IRB;
 - b. one physician.
6. Each designated IRB will have members possessing:
 - a. an understanding of the local community attitudes related to human research;
 - b. the professional competence and knowledge necessary to evaluate the research activities routinely reviewed by the Board;
 - c. an understanding of the acceptability of the proposed research in terms of commitments, regulations, applicable law, and standards of professional conduct and practice; and,
 - d. knowledge and experience in the issues related to research involving children, prisoners, pregnant women, and fetuses, incompetent or individuals with impaired decision-making capacity, or persons with life-threatening conditions

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who can neither give informed consent nor refuse enrollment in emergency research.

7. Each designated IRB may have the following additional members:
 - a. Representatives of affiliated institutions (institutions affiliated by "Memorandum of Understanding" (MOU).
 - b. Mental health advocates representing family members of persons affected by mental illness are sought as alternate voting members (who vote in the absence of a primary member), along with a prisoner representative.
 - c. Individuals with expertise in special areas beyond that of the Board members may be invited to assist with issues when needed. These consultants may not vote with the IRB. The need for an outside consultant is typically identified by the IRB Office staff or Chair during the pre-review process.

C. Chair

1. The President at the University designates the Chair for each Board from the membership. The Director of RRP makes Chair and alternate Chair appointment recommendations from the membership to the Institutional Official (IO), who is authorized to act on behalf of the institution as the responsible official for the HRPP. The IO then makes recommendations for appointment by the President of the University.
2. IRB Chairs and alternate Chairs serve on the Board for a term of up to two (2) years (which may be renewed).
3. The Chair is responsible for:
 - a. ensuring that the respective IRB carries out their responsibility to review each protocol for compliance with the requirements of 45 Code of Federal Regulations (CFR) Part 46 and, if applicable, 21 CFR Parts 50 and 56, 38 CFR Part 16, as well as all other applicable federal, state, and institutional regulations and policies;
 - b. conducting expedited review of human research or delegating this authority to qualified IRB member(s);
 - c. maintaining communication with the investigators and the IRB Office;
 - d. providing oversight and leadership in conducting review of alleged cases of non-compliance, reports of possible unanticipated problems, and reports of possible conflict of interest; and
 - e. chairing the convened IRB meeting.
4. For each IRB, a designated alternate Chair(s) assists the Chair in fulfilling the responsibilities listed above. In addition, as appropriate, the alternate Chairs may serve as primary reviewers in conducting expedited reviews. When necessary the

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Director of RRP or IRB Associate Director may serve as an alternate Chair if the designated Chair or alternate Chair is not available

D. Term of Membership

IRB members serve on the Committee for a term of up to three (3) years (which may be renewed). The University committee interest process allows individuals to volunteer for service. In addition, the Deans, Chairs and Directors of Schools and Centers may be asked to nominate individuals for Chair, alternate Chair, and member roles on the IRB after review of scholarly, scientific, and other credentials. The Director of RRP makes membership appointment recommendations to the IO who then makes recommendations for appointment by the President.

The appropriate institutional official from IRB-affiliated institutions may nominate representatives as full members to each IRB.

The IRB Office maintains appropriate documentation of qualification of each member, and membership rosters contain information on members to ensure appropriate representation at IRB meetings for each protocol under review.

IV. Definitions

There are no defined terms used in this Policy.

V. Related References

There are no related documents associated with this Policy.

VI. Review and Approval History

- A. The approving authority of this policy is the University Executive Committee.
- B. The review frequency cycle is set for three years following the last review date, a time period that is not mandated by regulatory, accreditation, or other authority.

Effective Date	Action Taken	Approved By	Date Approved
06/2000	Policy Origination		
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