



### I. 1.6.6 Institutional Review Board

Chapter 1 - Administration and Organization	Original Effective Date: June 2000
Section: 1.6 Administrative Committees	Date Last Reviewed: March 2026
Responsible Entity: Senior Executive Vice President for Research and Innovation	Date Last Revised: March 2026

### II. Purpose

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

### III. Scope

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

### IV. Policy

The IRBs are a component of the Institution'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 Institutional policies and federal and state regulations. Protections for human subjects are provided through prospective and continuing review and approval of the scientific and ethical issues related to research under the Institution's HRPP. See Institutional Handbook of Operating Policies (IHOP) [7.2.2 Institutional Review Board Responsibilities](#), which further specifies the accountabilities of the IRB.

#### B. Membership

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1. Each IRB consists of at least five (5) primary members, including a Chair. The IRB Director determines the actual number and composition of Board members after taking into consideration the nature and volume of research reviewed.
2. Primary members are assigned to a Board, and alternates are formally appointed based on a variety of professional, ethnic/racial, gender, scientific, and institutional affiliation backgrounds as required by 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 a primary member's absence and shall have expertise and qualifications similar to the primary member in whose place they will vote. Members shall be drawn from the various components of the Institution, from other institutions that rely on the IRB, and from the community at large.
4. Each designated IRB will have members representing:
  - a. a variety of scientific professions or backgrounds relevant to the research conducted at the Institution;
  - 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 Institution or other institutions that utilize the IRB;
  - b. one physician; and
  - c. one member from a non-scientific background.
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 feasibility, 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, individuals with impaired decision-making capacity, or persons with life-threatening conditions who can neither give informed consent nor refuse enrollment in emergency research.
7. Each designated IRB may rely on subject matter experts with varying expertise. These subject matter experts may be invited to attend meetings as guests, and may provide guidance or recommendations as needed. However, they may not vote with the IRB unless also appointed as members of the IRB. The need for an outside

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consultant is typically identified by the IRB Office staff or Chair during the pre-review process, and consultants may include (but are not limited to) the following:

- a. Representatives of affiliated institutions (institutions affiliated by "Memorandum of Understanding" (MOU)).
- b. Representatives of South Texas Veterans Health Care System (STVHCS).
- c. Consultants with expertise or personal experience in areas beyond that of the Board members.

### C. Chair

1. The President of the Institution or designee designates the Chair for each Board from among the membership. The IRB Director 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 Institution.
2. IRB Chairs and alternate Chairs serve on the Board for a term of two (2) years. Terms may be renewed without limit.
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 CFR 46 and, if applicable, 21 CFR 50 and 56, 38 CFR 16, and other applicable federal, state, and institutional regulations and policies;
  - b. conducting expedited review of human subjects research or delegating this authority to qualified IRB member(s);
  - c. maintaining communication with 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 conflicts 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 IRB Director or Associate Director may serve as an alternate Chair if the designated Chair or alternate Chair is not available, as long as the IRB Director/Associate Director has been appointed as an IRB member and alternate Chair by the Institution President.

### D. Term of Membership

IRB members serve on the Committee for a term of three (3) years. Terms may be renewed without limit. The Institutional 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 membership roles on the IRB after

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review of scholarly, scientific, and other credentials. The IRB Director makes membership appointment recommendations to the IO, who then makes recommendations for appointment by the President of the Institution.

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

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

## V. Definitions

When used in this document, the following words have the meaning set forth below unless a different meaning is required by context.

Institutional Official (IO) - Institutional official who is legally authorized to act on behalf of the institution and is responsible for ensuring compliance with federal, state, and local laws and regulations for human subjects research. The IO for UT Health San Antonio is the Senior Executive Vice President for Research and Innovation.

## VI. Related References

"Engagement of Institutions in Human Subjects Research," OHRP, 2008.

[IHOP 7.2.1 Human Research Protection Program Responsibilities](#)

[IHOP 7.2.2 Institutional Review Board Responsibilities](#)

## VII. Review and Approval History

The approving authority of this policy is the University Executive Committee.

Effective Date	Action Taken	Approved By	Approved Date
06/2000	Policy Origination		
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06/2021	Policy Revision		
03/2026	Policy Revision	Executive Committee	03/20/2026