

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 1	Administration and Organization	Effective:	June 2000
Section 1.6	Administrative Committees	Revised:	February 2009
Policy 1.6.6	Institutional Review Board	Responsibility:	President

INSTITUTIONAL REVIEW BOARD

Members

Each Health Science Center Institutional Review Board (IRB or Board) consists of a Chair and at least five (5) primary members and appropriate ex-officio members. The IRB Director determines the actual number and composition of Board members after taking into consideration the nature and volume of research reviewed. The Human Research Protection Program (HRPP) Steering Committee reviews the membership and composition at least bi-annually.

One primary member is assigned to a “class of membership” on every Board. Each primary position reflects the diverse professional, ethnic/racial, gender, scientific and institutional affiliation backgrounds required by the federal regulations and appropriate to the research routinely reviewed. One or more formally appointed alternates are assigned for each class of membership. Board members may be assigned to more than one Board; however, no member is permitted more than one vote at any meeting.

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 Health Science Center IRB and from the community-at-large to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

Each designated IRB will have members representing:

- multiple scientific professions or backgrounds;
- non-scientific professions or backgrounds;
- various racial/ethnic backgrounds;
- both genders; and,
- various cultural backgrounds.

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Each designated IRB will have at least:

- one member with no affiliation with the Health Science Center or other institutions that utilize the Health Science Center IRB;
- two members with VA affiliation, one of which must have scientific expertise; and,
- one physician.

Each designated IRB will have members possessing:

- an understanding of the local community attitudes related to human research;
- the professional competence and knowledge necessary to evaluate the research activities routinely reviewed by the Board;
- an understanding of the acceptability of the proposed research in terms of commitments, regulations, applicable law, and standards of professional conduct and practice; and,
- 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 who can neither give informed consent nor refuse enrollment in emergency research.

Each designated IRB may have the following additional members:

- Representatives of affiliated institutions (institutions affiliated by “Memorandum of Understanding” (MOU);
- Ex-officio members are members by virtue of their office or position and serve as full voting members. Mental health advocates representing family members of persons affected by mental illness are sought as ex-officio voting members, along with a prisoner representative. Other ex-officio, non-voting

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members may include the representative of the Health Science Center administration who may serve as legal counsel to the IRB.

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 the Chair during the pre-review process.

Chairs

The President at the Health Science Center designates the Chair for each Board from 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 Health Science Center. IRB Chairs and alternate Chairs serve on the Board for a term of up to two years (which may be renewed). The Chair is responsible for: (1) 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; (2) conducting expedited review of human research or delegating this authority to qualified IRB member(s); (3) maintaining communication with the investigators and the IRB Office; (4) 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 (5) chairing the convened IRB meeting.

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.

Charge

To ensure that the rights and welfare of research subjects are adequately protected and all activities involving human subjects are in

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compliance with Health Science Center 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 Health Science Center HRPP. See *Handbook of Operating Procedures* (HOP), [Section 7.2.2](#), "Institutional Review Board Responsibilities", which further specifies the accountabilities of the IRB.

Scope of the IRB

Health Science Center IRBs are a component of the HRPP and have authority over all non-exempt human research activities for Health Science Center faculty, staff, and/or students, considered 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., Health Science Center research activities outside the United States) or source of funding and includes as applicable any affiliated institution under an active [IRB Authorization Agreement Form](#). The IRB Director determines whether research is exempt from 45 CFR Part 46; the researcher may not make this determination. The IRB Director may delegate this authority to a designated reviewer.

Authorization

The President on behalf of the Health Science Center grants the authority of the IRB as established by federal regulations (e.g., 45 CFR 46 and 21 CFR 50 and 56).

Term of Membership

IRB members serve on the Committee for a term of up to three years (which may be renewed). The Health Science Center committee interest process allows individuals to volunteer for service. In addition, the Deans, Chairs and Directors of Schools and Centers are asked to nominate individuals for Chair, alternate Chair, and member roles on the IRB after 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. The VA Research and Development Committee nominates representatives from the South Texas Veteran's Health Care System (STVHCS) as full members (review all research) to each IRB. The

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STVHCS Director and the President of the Health Science Center jointly appoint VA members.

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

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