

HEALTH SCIENCE CENTER HANDBOOK OF OPERATING PROCEDURES

Chapter 7	Research and Sponsored Programs	Effective:	May 2008
Section 7.2	Human Research Protection Program	Revised:	August 2008
Policy 7.2.2	Institutional Review Board (IRB) Responsibilities	Responsibility:	President

INSTITUTIONAL REVIEW BOARD (IRB) RESPONSIBILITIES

Overview

The University of Texas Health Science Center at San Antonio (Health Science Center) has assured the Department of Health and Human Services (DHHS) of compliance with DHHS regulations (45 CFR § 46.103) for the protection of human subjects, through an Office of Human Research Protection (OHRP) approved Federalwide Assurance (FWA00005928). The FWA covers the Health Science Center, inclusive of the School of Medicine, the Dental School, the School of Nursing, the Graduate School of Biomedical Sciences, the School of Health Professions, centers, and organized research units.

Authority of the IRB

The University established the IRB in accordance with the *Handbook of Operating Procedures* (HOP), [Section 1.6.6](#), "Institutional Review Board". The Health Science Center grants its IRBs the authority to:

1. Approve or require modifications to secure approval or disapprove all research activities overseen and conducted by the organization.
2. To suspend or terminate approval of research not being conducted in accordance with the IRB's requirements or that has been associated with unexpected harm or increased risk to participants.
3. To observe, or have a third party observe, the consent process.
4. To observe, or have a third party observe, the conduct of the research.
5. To investigate allegations of non-compliance with institutional policies or research regulations for the protection of human subjects and reports of unanticipated problems. In cases where corrective actions is needed, the IRB may take appropriate actions, to include, but not limited to, requiring modifications, determining data collected cannot be used for publication, suspending or terminating approval, requiring additional education, disqualifying investigators from conducting research

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involving human subjects at the institution, and recommending to the institution’s administration that further administrative action be taken.

The IRB shall present these determinations to the Institutional Official (IO), in whom ultimate approval authority is vested (ultimate approval authority for affiliated institutions relying on a Health Science Center IRB is described in that institution’s FWA and “Memorandum of Understanding” (MOU) with the Health Science Center). Determination shall be presented in the form of IRB minutes presented for IO signature. The IO may accept, add additional restrictions to or reject some or all of the determinations of the IRB, with the exception that the IO cannot approve research involving human subjects that has not been approved by the IRB (e.g., tabled/deferred or disapproved by the IRB). Likewise, other officials or committees of the organization may not approve the research if it has not been approved by the IRB.

The authority granted to the Health Science Center IRBs is in accordance with the *Protection of Human Subjects, Code of Federal Regulations* (CFR), Title 45 Part 46 (45 CFR Part 46), 21 CFR Part 56 (and other applicable FDA regulations), and 38 CFR Part 16 (and other applicable VA regulations).

Where research includes information covered under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the IRB has authority to act as the Privacy Board to review, approve, require modifications in (to secure approval), or disapprove requests for alteration to individual authorization, waive individual authorization or partially waive required authorization for use or disclosure of protected health information as described in 45 CFR § 164.508.

Each IRB may be given a primary focus area (e.g., initial review or continuing review).

Independence of the IRB

The Health Science Center grants the IRBs the authority to act independently to bind all activities falling under the authority listed above. All Health Science Center personnel who become aware of attempts to inappropriately influence the IRB are to report such incidents to the IRB Director, who notifies the Assistant Vice President

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for Research Operations (AVPR) and the IO (if allegations involve these individuals, the President will be notified). The IO in consultation with the AVPR and IRB Director and other appropriate institutional officials will evaluate the allegation. If the allegation is validated they will determine the appropriate response and any action required will be taken by at least a department level supervisor. Responses may range from an oral or written reprimand up to and including suspension of the individual from some or all current or future research activities under the purview of the Health Science Center IRBs. The IO may refer the issue for additional institutional action.

IRB Policy Development

The IRB Director develops and implements written IRB policies and procedures under applicable regulations for the protection of human subjects, in consultation with the HRPP Steering Committee (See [HOP Section 1.6.14](#), "Human Research Protection Program (HRPP) Steering Committee").

Knowledge, Skills and Abilities of Members

The IRB Chairs, members (primary, alternate, and ex officio) and IRB Director and staff must be familiar with the ethical principles guiding human research; the requirements of federal regulations, applicable state law, the institution's FWA; and, institutional policies and procedures established for the protection of human subjects. The IRB as a whole, must also have effective knowledge of subject populations and other factors which can potentially contribute to a determination of risks and benefits to subjects and which can impact participants' informed consent.

New members to the IRB shall receive orientation from the IRB Chairs, Director, or designee. Members must complete required training as outlined in applicable IRB education policies. Members will also receive continuing education on current topics of human research as outlined in applicable IRB education policies. Members are educated on topics, such as ethics, applicable regulations, policies, etc. Each member shall receive continuing education information as part of the monthly IRB packets. Pertinent issues are discussed at meetings and documented in the minutes as appropriate.

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Removal of IRB Members

Members may be disqualified from the IRB for scientific misconduct, unethical behavior, conflict of interest, or non-compliance with the rules governing the IRB or failure to actively participate. Such concerns are forwarded to the IO for review and action, as appropriate.

Meetings

IRBs meet regularly to review and act on initial and continuing review, as well as review of requests for modification of approved research, reports on non-compliance or unanticipated problems for all non-exempt human research. The IRB Director establishes the schedule for meetings. The IRB Director, Chair, or IO may direct or convene additional meetings at any time.

Affiliated Institution Responsibilities

The Health Science Center IRBs may provide review and continuing oversight of some or all research conducted at affiliated institutions through a valid signed "[IRB Authorization Agreement Form](#)". Institutions relying on the Health Science Center IRBs remain responsible for ensuring compliance with the IRB's determinations and the terms of its OHRP approved FWA, as applicable.

Written procedures for reporting findings and actions to appropriate officials are documented in valid signed MOUs with institutions relying on the Health Science Center IRBs for all or most of their research.

Review of Policy

The HRPP Steering Committee shall review this policy bi-annually and submit recommendations for changes to the IO and the Executive Committee.
