I. 7.2.1 Human Research Protection Program Responsibilities

Chapter 7 - Research and Sponsored Programs	Original Effective Date: April 2008
Section: 7.2 Human Research Protection Program	Date Last Reviewed: March 2026
Responsible Entity: Senior Executive Vice President for Research and Innovation	Date Last Revised: March 2026

II. Purpose

The Human Research Protection Program (HRPP) encompasses the entities that contribute to the mission to protect the rights and welfare of participants who take part in UT Health San Antonio (Institution) Research.

III. Scope

This policy applies to all Workforce Members—including faculty, staff, students, residents, healthcare providers, and researchers of any UT Health San Antonio–controlled affiliate, including but not limited to its schools, clinics, hospitals, and research activities.

IV. Policy

The President of the Institution or designee has delegated the authority and responsibility to establish, maintain, and advance the HRPP to the Senior Executive Vice President for Research and Innovation (VPR) as the Institutional Official (IO).

A. HRPP Administration

The responsibility for the protection of human participants is shared among a number of organizational components that conduct Research, as well as those responsible for program administration of the HRPP. The VPR Executive Leadership is responsible for integrating the policies and procedures of the institution and addressing issues across the organizational components.

The VPR Executive Leadership assures that the essential organizational representatives are brought together to address the overall program requirements, and to evaluate the program's effectiveness. The IRB Director is responsible for the day-to-day operation of the program and disseminating program information.

B. Research Covered by the HRPP

1. The HRPP covers activities that are defined as human subject research. Any Research involving human subjects that is conducted on or off site by an Institutional employee or agent is subject to the Institutional HRPP, Institutional policies, and review by a designated Institutional Review Board (IRB). This applies to any investigation and/or data collection for Research purposes which involves human subjects, regardless of the funding source made to the institution or to an employee of the institution. The federal regulations provide guidance to properly characterize human subject research. It should meet the Department of Health and Human Services (DHHS) definition of both "Research" and "Human Subjects", or in the case of Research regulated by the Food and Drug Administration (FDA), it should meet the FDA definition of both "Human Subject" and "Clinical Investigation".
2. Research participants covered by the Institution's HRPP may include the following: healthy volunteers, patients, students, children, non-English speaking, pregnant women, prisoners, and the mentally and decisionally impaired, including those who are institutionalized. The term "Research" can pertain to basic and applied investigations, such as bench testing or evaluation, clinical Research, product development, and similar activities. The term Human Subject Research or Human Research Participant may be applicable to a variety of activities:
    a. Behavioral and social sciences Research (e.g., surveys, interviews, observations, and studies of existing records)
    b. Clinical trials testing an investigational article
    c. Epidemiological Research, including surveillance, monitoring, and reporting programs
    d. Pilot studies
    e. Thesis and dissertation Research involving human volunteers
    f. Repository Research, tissue banking, and databases storing information from individually identifiable, living persons
    g. Human genetic Research
3. The Institution's IRB Office provides guidance and is responsible for determining whether a project meets the regulatory definitions for human Research. The IRB Office provides written policies and procedures for the Research community to follow in determining whether activities need IRB review or are exempt from review. The IRB Office reviewers for exemption determination may recommend revisions within an exempt project to enhance subjects' protection. Although proposed Research may qualify for exemption, the sponsor or the IRB may require that it receive full or expedited review. Investigators conducting Research that is exempt from federal regulations may also incorporate consent and other procedures to maintain human Research protections. Institutional investigators may not determine whether Research is exempt from the federal regulations, including IRB review.

C. Ethical and Legal Principles in Conducting Research

The supporting ethical principles for the Institutional HRPP are set forth in the Belmont Report, entitled "Ethical Principles and Guidelines for the Protection of Human Subjects of Research." The Belmont Report establishes three guiding principles: respect for persons, beneficence, and justice. The integrity of the Research is also maintained by ensuring that the Principal Investigator and Research team members are qualified by education and training to conduct the Research, and that they adhere to the IRB-approved protocol defining the Research.

1. The HRPP adheres to regulations applicable to protecting the rights of human participants, to include:
    a. DHHS 45 CFR Part 46, Protection of Human Subjects (Common Rule)
    b. DHHS 45 CFR Parts 160 and 164, Standards for Privacy of Individually Identifiable Health Information (HIPAA Privacy Rule)
    c. FDA 21 CFR Part 50, Protection of Human Subjects, and Part 56, Institutional Review Boards
2. Research involving investigational drugs or biologics falls under FDA regulations, including 21 CFR Part 312, Investigational New Drug Application, and Part 314, Applications for FDA Approval to Market New Drugs. Research involving investigational devices falls under FDA regulations including 21 CFR Part 803, Medical Device Reporting, Part 812, Investigational Device Exemptions, and Part 814, Pre-market Approval for Medical Devices.
3. The applicability of state and local laws must be considered.
4. Appropriate financial disclosures and conflict of interest considerations in clinical Research fall under the FDA 21 CFR Part 54, Financial Disclosure by Clinical Investigators and disclosed in accordance with UT Health San Antonio Institutional Handbook of Operating Policies(IHOP) 10.1.6 Conflicts of Interest in Research and Disclosure.
5. For Research funded by or covered by federal agencies such as the U.S. Department of Education, U.S. Department of Defense, National Science Foundation, or U.S. Veterans Affairs, the institution applies additional regulations and policies on a case-by-case basis as appropriate to the agency or sponsor.

The Office of the VPR holds the primary responsibility for policies and educational programs communicating the ethical and legal principles to which Research personnel must adhere in conducting clinical Research. Research must comply with all applicable federal and state laws and regulations. The organizational components of the Institutional HRPP shall develop and implement policies and procedures related to human Research protection in alignment with this ethical and regulatory framework. The Institution maintains an IRB Authorization Agreement with affiliates and other institutions outlining responsibilities regarding human Research.

D. Research Review

It is Institutional policy to review all Human Subject Research conducted by employees or agents of the Institution irrespective of location, source of funding, or exempt status.

This review is intended to foster high ethical standards in the conduct of Research and to apply criteria to protect the human participants who take part in Research. In support of this obligation, the Institution has three registered IRBs. With approvals and written agreements, the institution may also use the IRB of another organization to ensure effective and timely Research review or to comply with federal agency policies requiring single IRB review.

1. The IRB proceedings and implementation of policies must be free of undue influence or coercion to maintain the reliability and integrity of the IRB process. Concerns of undue influence or coercion should be reported to the IRB Director or the Office of the VPR.
2. The IRB Director is responsible for establishing and maintaining policies and procedures to ensure: 1) that all information necessary to adequately review the Research is provided by investigators, and 2) that the members of the IRB have the guidance and the process requirements necessary to fully evaluate the validity of the Research. The IRB Office maintains policies and procedures for the HRPP that describe the IRB practices for conducting reviews and approvals of human Research in accordance with applicable regulations and institutional policies. These policies include, but are not limited to, the following:
    a. determining whether the proposed Research may be expedited, requires convened IRB review, or is exempt in accordance with the federal regulations and guidance;
    b. developing informed consent processes and documentation, ethical considerations, and policy related to vulnerable populations;
    c. requirements for data and safety monitoring;
    d. emergency use of an investigational drug/device, or humanitarian use device;
    e. determinations and reporting processes for unanticipated problems involving risks to subjects or other (UPIRSO); and
    f. non-compliance, suspensions, or terminations of Research approval.
3. The department Chairs and center Directors are responsible for attesting to the soundness of the Research plan, competency of the investigator(s) to conduct the project, and resources sufficient for execution of the Research and protection of Research participants.
    a. Processes to support these assurances may include internal review committees or specialized review criteria within departments, institutes, or centers. If the Principal Investigator (PI) fails to meet their responsibilities, the department Chair or center Director is the point of contact for correction of deficiencies.
    b. The institutional approval process for sponsored Research confirms at multiple organizational levels (e.g., department, center, and Dean) that there is agreement on the type and amount of resources required for the Research and that it meets the goals and objectives of those organizational levels.
4. The IRB Office establishes policy and, in conjunction with other VPR offices, offers education and consultation for institutional investigators conducting FDA-

regulated and non-FDA-regulated human research. When an investigator takes on sponsor responsibilities and/or is using an investigational article that may require an IND or IDE, the appropriate office(s) within the Office of the VPR will advise the Research team and assess the Research facilities to ensure the regulatory requirements are supported.

5. The Office of the VPR conducts quality assessments for purposes of continuous improvement and compliance with institutional, federal, state, and local policies and regulations, as well as adherence to Research best practices. Applicable guidance may include, but is not limited to, International Conference on Harmonization (ICH) Good Clinical Practices (GCP), Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), 21 CFR Part 11 requirements for electronic records, Quality System Regulations (QSR), and Centers for Medicare & Medicaid Services (CMS).

   The results of the reviews are shared with the IRB Director so that corrective actions in areas of non-compliance may be addressed. If the Office of the VPR receives requests to conduct for-cause audits or reviews, the IRB Director and appropriate Dean and/or Chair are notified.

6. The Biological Safety and Radiation Divisions within the Environmental Health and Safety Office provide expertise and consultation for human research, to include compliance with federal, state, and local regulations. As applicable, prior to study activation, these divisions review and approve Research protocols through the Institutional Biosafety, Radiation Safety, and Radioactive Drug Research Committees.

E. Investigator Responsibilities

PIs are ultimately responsible for protecting the rights and welfare of study participants enrolled in their Research. PIs are responsible for ensuring all Research personnel are trained and knowledgeable of associated protocols and applicable regulations. All investigators and Research staff must be knowledgeable of the HRPP, to include applicable regulatory requirements, Institutional policies and procedures, and policies of the IRB, Clinical Trials Office (CTO), and Office of Sponsored Programs (OSP). Investigators are responsible for complying, and ensuring compliance, with all applicable policies and regulations as well as adhering to the IRB-approved protocol.

Institutional policy requires those engaged in conducting human Research to successfully complete and periodically renew mandatory training in the protection of human subjects; this includes those conducting Research exempt from federal regulations.

F. Sponsor Agreements

When Human Subject Research is sponsored by an external sponsor or organization, both the Institution and the sponsor have obligations to protect Research participants. The OSP policies and procedures on written agreements with sponsors require the following:

1. Affirmation that the institution will follow the IRB-approved protocol and applicable law.
2. Provision of medical care for any Research-related injury for participants.
3. Timely reporting (within 30 days) from sponsor to both the Institution and the PI, for the duration of the study and for two years thereafter (or such longer period as may be warranted by circumstances or law), of any findings that may affect the safety of participants or their willingness to continue the study, influence the conduct of the study, or change the IRB's approval of the Research.
4. Plan for distributing the findings of the Research and procedures for publication.
5. Details on how participants will be notified of any potential impacts to their safety or medical care which are a direct result of participating in the study.

G. Research Participant Interactions

The IRB Office provides policy and guidance on interactions between Research team members and study participants before, during, and after the conduct of a study (e.g., recruitment, screening, consenting). The Research team must provide opportunities for participants or their designated representative to voice questions, concerns, or complaints regarding the study to either an investigator, study team member, or an informed individual unaffiliated with the Research. These communications must be confidential and supported by processes to ensure that the concerns are handled. Multiple modes of inquiry (e.g., phone, e-mail, hotlines) should be available to current, former, and prospective participants. Various participant outreach efforts should be instructive in nature and designed to communicate effectively to the community being served. The VPR Leadership will conduct periodic review of various outreach efforts to advance quality improvement.

H. Supporting Institutional Programs

1. The IO, assisted by the VPR Executive Leadership, is responsible for ensuring integration of these programs in support of the protection of human subjects participating in Research.
2. VPR Executive Leadership is responsible for developing policy that defines Research misconduct and states the institutional processes and consequences for Research misconduct that are applicable to those who conduct Research involving human subjects under the auspices of the Institution.
3. The Institutional Compliance and Privacy Office (ICPO) and Office of Legal Affairs are responsible for multiple aspects of the Institution's programs and policies concerning HIPAA, ethics, standards of conduct, and conflict of interest.

V. Definitions

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

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DHHS Definitions:

Research – a systematic investigation including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. (45 CFR 46.102(l))

Human Subject – a living individual about whom an investigator (whether professional or student) conducting Research: (1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. (45 CFR 46.102(e(1))

FDA Definitions:

Clinical Investigation – involves the use of an investigational article (i.e., drug, device, food substance or biologic) and one or more Human Subjects. This applies to test articles that require prior submission to the FDA and those that do not. The results of the investigation may be intended to be part of an application for a Research or marketing permit. It does not include the use of FDA-approved devices or drugs in routine medical practice. (21 CFR 56.102(c))

Human Subject – an individual who is or becomes a participant in Research, either as a recipient of the test article or as a control. A human subject may be either a healthy individual or a patient (21 CFR 56.102(e)) or an individual (healthy or otherwise) on whom, or on whose specimen, an investigational device is used (21 CFR 812.3(p))

VI. Related References

Office of the Vice President for Research:
https://uthscsa.edu/research

Institutional Handbook of Operating Policies (IHOP):
1.3.7 Vice President for Research
1.6.6 Institutional Review Board
7.6.1 Research Misconduct
10.1.6 Conflicts of Interest in Research and Disclosure

Enterprise Research Management System (ERMS) IRB Library:
HRP-101 - Human Research Protection Program Plan
HRP-103 - Investigator Manual

VII. Review and Approval History

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

Effective Date	Action Taken	Approved By	Approved Date

04/2008	Policy Origination		
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06/2021	Policy Revision		
03/2026	Policy Revision	Executive Committee	03/20/2026