The University of Texas at San Antonio
Handbook of Operating Procedures
Chapter 10 – Research

10.10 Human Research

I. POLICY STATEMENT

The University of Texas at San Antonio (UTSA) is committed to protecting the rights and welfare of human subjects in research by adopting the ethical principles set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (entitled: Ethical Principles and Guidelines for the Protection of Human Subjects of Research [the "Belmont Report"]). This policy requires all faculty, students, and staff who conduct Human Subjects Research on behalf of UTSA to follow these principles as supported by the University's human research protection program.

II. RATIONALE

Ethical principles for the use of humans in research are embodied in federal regulations and administered by the Department of Health and Human Service's Office of Human Research Protections. Research conducted on behalf of UTSA will comply with the applicable federal regulations and any additional protections imposed by oversight and/or sponsoring agencies. This policy also requires compliance with UTSA's Federalwide Assurance (FWA 00003861) for any Human Subjects Research to which it applies.

III. SCOPE

This policy requires all faculty, students, staff, and investigators who conduct Human Subjects Research on behalf of UTSA to follow these principles as supported by the University's human research protection program.

IV. WEBSITE ADDRESS FOR THIS POLICY

https://www.utsa.edu/hop/chapter10/10-10.html

V. RELATED STATUTES, POLICIES, REQUIREMENTS OR STANDARDS

A. UTSA Human Research Protections Program Policies and Guidance
B. UTSA HOP Policy 10.04, Conflicts of Interest in Research & Intellectual Property
C. Department of Health and Human Services, *Protection of Human Subjects* 45 CFR Part 46
D. Department of Health and Human Services, *Promoting Objectivity in Research* 42 CFR Part 50 Subpart F
E. Food and Drug Administration, *Protection of Human Subjects* 21 CFR Part 50
F. Food and Drug Administration, *Institutional Review Boards* 21 CFR 56
G. Ethical Principles and Guidelines for the Protection of Human Subjects of Research, The Belmont Report.

VI. CONTACTS

If you have any questions about research with human subjects, contact the following office(s):

The Office of Research Integrity
210-458-6473 or irb@utsa.edu

VII. DEFINITIONS

See definitions listed in the IRB office policy, HRP-001: Definitions.

VIII. RESPONSIBILITIES

See responsibilities described in the IRB office policies posted to the IRB office website, including:

- HRP-010: Human Research Protection Program,
- HRP-800: Investigator Obligations,
- HRP-801: Prompt Reporting Requirements,
- HRP-802: Informed Consent,
- HRP-803: Documentation of Informed Consent, and
- HRP-910: Investigator Manual.

IX. PROCEDURES

Standard Operating Procedures for the Human Research Protection Program are posted to the IRB office website. These procedures describe requirements for researchers, IRB members, and designated staff responsible for supporting the Human Research Protection Program.

Any changes to Standard Operating Procedures that directly affect investigators will be developed in consultation with a human subject faculty advisory group including representation from or appointed by UTSA faculty senate.

XI. FORMS AND TOOLS/ONLINE PROCESSES

Forms, checklists, and worksheets for new and continuing research are found on the IRB office website.