15.99.01.01 USE OF HUMAN SUBJECTS IN RESEARCH

Revised: November 22, 2019

Next Scheduled Review: November 22, 2024

RULE STATEMENT

Texas A&M University-San Antonio (A&M-San Antonio or University) adheres to the laws, regulations, procedures, and ethical practices that ensure the privacy, safety, health, and welfare of human subjects involved in research. This rule applies to all human subject research conducted under the auspices of A&M-San Antonio, including survey research, without regard to where the research occurs, whether or not the research is funded, or who the investigator is (*i.e.*, employee, student, or third party).

RULE

1. ADMINISTRATIVE REQUIREMENTS

   1.1 A&M-San Antonio follows a consistent set of procedures and safeguards to protect human research subjects. The University's practices do not depend on whether the research is funded or the source of funding the University may receive.

   1.2 A&M-San Antonio's Institutional Review Board (IRB) must review and approve a proposed research project involving human subjects, whether the research is funded or unfunded, before the project commences.

   1.3 IRB approval is required for all human subject research conducted under the auspices of A&M-San Antonio.

   1.4 The IRB, investigators, and others involved in human subject research shall honor the University's Federalwide Assurance approved by the Office of Human Research Protections.

   1.5 The IRB shall post to the University's website written procedures governing the review and approval of human research protocols and the reporting requirements applicable to human research projects.

2. GENERAL GUIDELINES

2.1 The principal investigator and chair of the department overseeing a research project involving human subjects are jointly responsible for submitting to the IRB a protocol for review and approval, even if the research is deemed exempt under federal law.

2.2 The principal investigator shall comply with continuing IRB review procedures and submit information, updates, and protocol amendments as required.

2.3 The principal investigator shall abide by the IRB's reporting requirements.

2.4 The Vice Provost for Research and Graduate Studies serves as the Institutional Official (IO) for A&M-San Antonio. The IO shall administer the University's human research protection program and ensure compliance with the laws, regulations, procedures, and ethical practices pertaining to human subject research. If the Vice Provost for Research and Graduate Studies position becomes vacant, the Provost or the Provost's designee shall serve as the IO on an interim basis until the position is filled or the President makes a new appointment.

2.5 The IRB reports to the IO. Through its authority to review and approve research protocols, the IRB shall protect the privacy, safety, health, and welfare of human research subjects.

RELATED STATUTES, POLICIES, OR REQUIREMENTS

System Regulation 15.99.01, Use of Human Subjects in Research

A&M-San Antonio Procedure 15.99.01.O0.01 Human Subjects in Research

45 C.F.R. Part 46 (Protection of Human Subjects)

21 C.F.R. Part 50 (Protection of Human Subjects) and Part 56 (Institutional Review Boards)

The Belmont Report, April 18, 1979 (Ethical Principles and Guidelines for the Protection of Human Subjects of Research)

Federal Policy for the Protection of Human Subjects (Common Rule)

Additional U.S. Food and Drug Administration Regulations (Good Clinical Practice and Clinical Trials)

42 U.S.C. § 289 (Institutional Review Boards; ethics guidance program)

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