Rule Statement

Texas A&M University-San Antonio (TAMU-SA) and all its faculty, students and staff shall comply with the applicable laws relating to human subjects research. The university acknowledges and accepts its responsibilities for ensuring that the privacy, safety, health, and welfare of human subjects are adequately protected. All research, which involves any form of participation of human subjects, qualifies as human subject research. This includes certain survey research, research by students as well as by faculty and staff and both internally and externally funded research.

Reason for Rule

This rule provides guidance in complying with federal law related to research with human subjects, including upholding the ethical principles and guidelines set forth in The Belmont Report, April 18, 1979, for the protection of human subjects of research.

Procedures and Responsibilities

1. ADMINISTRATIVE REQUIREMENTS

1.1 Procedures for safeguarding the rights of individuals shall be consistent regardless of sources of funding.

1.2 The Director of Graduate Studies and Research shall develop an Institutional Review Board (IRB). The IRB shall meet the requirements set out in the federal regulations and register with the Office of Human Research Protections (OHRP) of the U.S. Department of Health and Human Services. All research involving human subjects, whether funded or unfunded, must be reviewed by the IRB before initiation of the research project.

1.3 Texas A&M University-San Antonio shall obtain a Federal-wide Assurance (FWA) from OHRP.

1.4 Texas A&M University-San Antonio shall develop written IRB procedures, including procedures relating to the review of human subject research protocols and reporting guidelines. A specific protocol shall be developed for each
project. Each protocol shall be reviewed by Texas A&M University-San Antonio IRB for human subjects before initiation of the research project.

2. GENERAL GUIDELINES

2.1 Principal investigators and department chairs are responsible for ensuring that all research involving human subjects (including protocols which may be exempt, as defined in the federal regulations) is submitted to the IRB for review and approval.

2.2 Principal investigators shall submit continuing reviews to the IRB as directed by the IRB.

2.3 For research projects involving more than one system member or institution of higher education, all respective IRBs must approve the protocol, unless there is:

(a) a joint review arrangement;
(b) reliance upon the review of another qualified IRB; or
(c) similar arrangements for avoiding duplication of effort.

If the research involves federal funding and (a), (b) or (c) is utilized, the review process must be approved by the federal funding agency.

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Related Statutes, Policies or Requirements

System Regulation 15.99.01 Use of Human Subjects in Research

45 C.F.R. Part 46

21 C.F.R. Part 50 and Part 56

The Belmont Report, April 18, 1979

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

Additional U.S. Food and Drug Administration Regulations

42 U.S.C. 289

5 U.S.C. 301

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