

Texas A&M University-San Antonio

15.99.01.00.01 Human Subjects in Research

Approved: May, 19, 2011

Reviewed: April, 2013

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Next Scheduled Review: May, 2020

Reason for Procedure

Texas A&M University-San Antonio (A&M-San Antonio) recognizes the need for research activities in which human beings serve as research subjects. The University acknowledges and accepts its responsibilities for ensuring that the privacy, safety, health, and welfare of such subjects are adequately protected. All research, which involves any form of participation of human subjects qualifies as human subjects' research. This includes certain survey research, research by students as well as by faculty and staff, research projects in which the principal investigator(s) are not affiliated with the University, and all research involving human subjects regardless of the locus of its funding (i.e., internal or external). This Procedure is required by System Regulation [15.99.01 Use of Human Participants in Research](#).

Official Procedure

1. GENERAL

- 1.1 A&M-San Antonio complies with regulations of the Department of Health and Human Services (DHHS) for the protection of human subjects involved in research (45 CFR 46; <http://ohsr.od.nih.gov/guidelines/45cfr46.html>). These regulations, as defined by DHHS, are applicable to all research involving human subjects for which the University is responsible, regardless of whether the research is funded or not (and if funded regardless of the source of funding). In the case of funded research, if a conflict exists between regulations of the funding agency and DHHS the more restrictive regulations shall prevail.

2. INSTITUTIONAL REVIEW BOARD (IRB)

- 2.1 All research involving human subjects done under the auspices of A&M-San Antonio, including cooperative research conducted with any public or private entities must be reviewed and approved by the Institutional Review Board (IRB). Members of the Board are appointed by the Director of Graduate Studies.

3. HUMAN SUBJECT REVIEW AND APPROVAL

3.1 The IRB review and approval process shall be conducted in accordance with all Federal, State, System and University rules, policies, regulations and laws that govern the use of human subjects in research. The requirement for IRB review and approval applies to all research studies (in all University locations) using human subjects. IRB approval is required for all such studies (funded or non- funded) conducted by faculty, students, or staff. Review and approval are also mandatory for research proposed by persons unaffiliated with the University who wish to use as subjects persons who fall under the protection of the University (such as students, staff, or patients). No contact with human subjects (or prospective subjects) may be conducted and no study will be initiated before the study has been approved by the IRB.

3.2 A&M-San Antonio recognizes the ethical principles, considerations, and concerns expressed 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 \(The Belmont Report\)*](#).

3.3 The IRB will review all previously approved research projects at intervals appropriate to the degree of risk (as determined by the IRB), but not less than once per year.

4. HUMAN SUBJECTS ASSURANCE

4.1 A&M-San Antonio is committed to a policy of safeguarding the rights and welfare of human subjects and hereby gives assurance that it will comply with the Department of Health and Human Services (DHHS) regulations.

5. HUMAN SUBJECTS RESEARCH POPULATIONS

5.1 Special precautions will be taken to protect the rights and welfare of human subjects when research involves vulnerable populations. The nature of such precautions will depend upon the type and extent of vulnerability of subjects involved but shall be based upon respect for persons and concern for their welfare and be in accordance with Federal, State, and University regulations.

6. STUDENT RESEARCH INVOLVING HUMAN SUBJECTS (NON-MEDICAL)

6.1 Student research projects are reviewed using the same principles and guidelines followed by the IRB for the protection of human subjects in general. Any student-initiated and/or student-conducted research using human subjects, intended or likely to produce generalizable results, requires IRB approval. All students conducting research projects that require IRB approval must have a faculty supervisor. Requirements for IRB review and approval also applies to graduate theses and dissertation research and honors theses. Responsibility for obtaining IRB approval

for student research resides equally with the student and the faculty advisor/supervisor.

Related Statutes, Policies, or Requirements

System Regulation [15.99.01 Use of Human Participants in Research](#)

A&M-San Antonio Rule [15.99.01.01 Use of Human Subjects in Research](#)

[Institutional Review Board](#)

Definitions

Dependent Subjects: Dependent subjects include such individuals as the mentally or physically disabled, pregnant women, fetuses, minors, prisoners, parolees, addicts, and others in conditions of dependency.

University Students as Subjects: University students are vulnerable populations when a decision to participate as subjects is perceived to be required to prevent discrimination either in determination of course grades or in other activities of an academic unit or department. Researchers must take efforts to avoid coercion and the appearance of coercion.

Foreign Cultures: When research takes place involving subjects who belong to a foreign culture, the ethical principles and cultural traditions of that society will be identified and respected, including use of the native language (if subjects are not fluent in English) when providing information that potential subjects may use to decide whether or not to participate in a research study.

Laboratory Personnel: By virtue of their dependent positions, University laboratory personnel represent a vulnerable population with regard to acting as research subjects. Participation by such personnel should be entirely voluntary. The principal investigator(s) should make efforts to avoid any statements or actions that may be perceived as coercive regarding requests for laboratory personnel to participate in research studies involving even minimal risk. Compensation of individuals who are members of the University academic staff or regular exempt staff is governed by System Policies and Regulations, and University Procedures.

Contact Office

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