[Minor revisions: February 25, 2014]

# Angelo State University
**Operating Policy and Procedure**

**OP 56.03: Protection of Human Subjects in Research**

**DATE:** February 25, 2014

**PURPOSE:** The purpose of this Operating Policy/Procedure (OP) is to allow for the protection of human subjects involved in research conducted by Angelo State University faculty, staff, and students, in a manner consistent with federal regulations as stated in 45 CFR 46, Protection of Human Subjects (revised October 1, 2013), or any subsequent federal regulation relating to the subject matter of this OP.

**REVIEW:** This OP will be reviewed by May 1 every three years, or as needed, by the chair of the IRB Committee and the dean of the college of graduate studies with recommendations for revision presented to the provost and vice president for academic affairs by June 1.

## POLICY/PROCEDURE

### 1. Authority
**Title 45, Part 46, *Code of Federal Regulations***

Angelo State University has established an institutional review board (IRB) and procedures for the review of research involving human subjects in compliance with 45 CFR 46.

### 2. Research Involving Human Subjects

a. Angelo State University has prepared a document entitled "Policy and Procedures for the Protection of Human Subjects in Research" (Attachment) that is applicable to all research activity conducted at or sponsored by the university that involves human subjects, i.e., living individuals about whom an investigator (whether professional or student) conducting research obtains (a) data through intervention or interaction with the individual, or (b) identifiable private information. The policy is applicable to research involving human beings whose physical, emotional, or behavioral condition, responses, tissues, or fluids are investigated for any purpose other than for the sole purpose of benefiting the subject as an individual. It is applicable to the use of interviews, tests, observations, and inquiries designed to elicit or obtain non-public information about individuals or groups.

b. University employees who have an interest in pursuing research involving human subjects should plan the research project in compliance with the Policy and Procedures for the Protection of Human Subjects in Research. Prior to initiating a research project or conducting any research involving human subjects, the researcher must submit a proposal to the Institutional Review Board (IRB) and receive the approval of the IRB.

c. Human subjects, who must be voluntary participants in such research, are free to ask questions and withdraw from participation at any time. They may have access to a copy of the Policy and Procedures for the Protection of Human Subjects in Research. Human subjects may take grievances to the department chair and, if the matter remains unresolved, to the dean of the college. Grievances that are not resolved by the dean of the college may be pursued with the IRB through the grievance procedures specified in the IRB approved proposal document that governs that particular study.

d. The Institutional Review Board communicates with the ASU faculty using a specialized site on the University's Blackboard course management system. All forms necessary to complete a proposal to the IRB as well as instructions concerning the process can be found there and are maintained by the chair of the IRB committee. Individuals who do not have access to the University's Blackboard site may contact the dean of the college of graduate studies to request copies of these forms.

**3. Registration of the Institutional Review Board**

In accordance with 45 CFR 46, Subpart E., the Institutional Review Board must be registered with the U.S. Department of Health and Human Services' Office for Human Research Protections (OHRP). The chair of the IRB is responsible for maintaining this registration, including:

a. Renewing the registration every 3 years,

b. Updating the registration within 90 days after changes occur regarding the contact person or chair of the IRB.

Attachment: Policy and Procedures for the Protection of Human Subjects in Research