



Angelo State University
Operating Policy and Procedure

OP 56.03: Protection of Human Subjects in Research

DATE: February 22, 2021

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 the current version of 45 CFR 46, Protection of Human Subjects 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 and research 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, including collection and analysis of biospecimens (e.g., blood, saliva), 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.

[Major revisions: February 22, 2021]

- c. Human subjects, who must be voluntary participants in such research, are free to ask questions and withdraw from participation at any time without penalty. They may have access to a copy of the Policy and Procedures for the Protection of Human Subjects in Research. Human subjects may report and address grievances Human subjects may report and address grievances in accordance with the Policy and Procedures and 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 learning 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. Individuals who do not have access to the University's Blackboard site may access the forms online at <https://www.angelo.edu/irb>.

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](#)