



Angelo State University
Operating Policy and Procedure

OP 56.03: Protection of Human Subjects in Research

DATE: September 1, 2007

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, 2002), or any subsequent federal regulation relating to the subject matter of this OP.

In conjunction with these federal regulations, Angelo State University has established an institutional review board (IRB) as required by 45 CFR 46.

REVIEW: This OP will be reviewed by February 1 of each odd-numbered year by the chair of the IRB Committee and the director of research with recommendations for revision presented to the provost and vice president for academic and student affairs by March 1.

POLICY/PROCEDURE

1. Research Involving Human Subjects

- a. Angelo State University has published a document entitled "Policy and Procedures for the Protection of Human Subjects in Research" which is applicable to all research activity conducted at or sponsored by the University which 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. Copies of the Policy and Procedures for the Protection of Human Subjects in Research are available from the Dean of the Graduate School who serves as chairperson 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 Head and, if the matter remains unresolved, to the Dean of the College. Grievances which are not resolved by the Dean of the College may be pursued with the IRB through the grievance procedures specified in Part V, Section F, of the Policy and Procedures for the Protection of Human Subjects in Research.