ANGELO STATE UNIVERSITY
Institutional Review Board

HUMAN SUBJECTS REVIEW FORM FOR NEW OR PERIODIC REVIEW

Please complete this form and the required informed consent form. Print a copy for your records as well.

Principal Investigator (PI)

PI Department

Campus Address

Primary Phone

Primary E-mail

Project Title

Proposed Initiation Date

Project will be valid for one (1) year upon approval unless changes are made that require further IRB review.

Student-led Projects

If the Principal Investigator is a student, please provide the following information:

Faculty Advisor/Mentor

Student Classification (check one) Undergraduate Graduate

Funding Source

This research is supported in whole or in part using internal/external grants or other funding sources.

If you checked the box above, you must complete the field below.

Source(s)

Special Conditions

This research will use populations other than the ASU student participant pool(s).

If you checked the box above, approval from other IRB committees may be required before the project can initiate. This must be discussed in your summary of proposed activities.

This proposal describes a series of studies on a particular topic (programmatic research)

Research that is programmatic should include all possible experimental manipulations and measures that could be used within the context of the program. Programmatic research must be reviewed annually and any novel methods, measures or conditions must be presented to the Board before they are used. The Board recognizes that programmatic research does involve some ambiguity regarding future directions and will take that into account in its review.

Please provide a description of your project by responding to the following categories. Cut and paste the summary in the spaces provided below. If additional space is needed, you may e-mail additional pages to the IRB chair (contact the Sponsored Projects Office for that information).

General Summary: Provide a brief summary of the proposed research activity or program. Include the primary research question and a brief description of the proposed strategy to answer the question. Include a small set of core references (cited in the text) connecting your project to the extant literature. Include information about any collaborators, including whether students will be utilized as experimenters.

Finally, any and all of the following issues MUST be stated in this section: intent to use any substance that may be ingested or absorbed, intent to remove bodily fluids or tissue, intent to use disadvantaged populations and/or populations who cannot legally give consent. *If the research does not involve any of these issues, you MUST explicitly state that in your Summary statement*.

Summary

Detailed Description of Methodology: Provide details about the experimental methodology that you will employ in your study or research program. This section *MUST* be organized into separate paragraphs and labeled as follows: A) Participant information (populations utilized, recruitment procedures, number of participants to be recruited, conventions for anonymity and confidentiality of data); B) Measures (measurement devices, information about validity and reliability, necessary references and justifications for use); C) Procedures (track a hypothetical participant through the study; if you are describing programmatic research, include examples of how this hypothetical track could be altered based on preliminary findings); D) Special Topics (intent to use deception, protections for special populations or invasive procedures).

Procedures

Procedures for PI Contact: In this section, describe how inquiries, complaints and/or grievances concerning the proposed study will be addressed. This section *MUST* be organized into two separate paragraphs and labeled as follows: A) Addressing Participants (how you will address inquiries, complaints, and/or grievances concerning the study, including a description of where you will provide participants with the contact information for the PIs and the IRB administrator [consent form, debriefing form, etc.]); and B) Participant Debriefing (how you will debrief the participants and give them access to information about the study's results).

Procedures for Grievance

I am familiar with the policies and procedures of Angelo State University and 45 CFR 46 regarding human subjects. I subscribe to these standards and will adhere to them at all times.

I understand that approval of the project as described herein in no way permits the researcher to alter the research program or study beyond the constraints placed on the Board's approval and/or the constraints on human subjects research as outlined in 45 CFR 46. Unapproved deviation from the approved protocols as contained in this document that increases participant risk is STRICTLY PROHIBITED.

Principal Investigator Signature (type names of each principal investigator)

I (We) affirm that the signature above was completed by the person(s) named therein.

For Student-Led Projects

Faculty Advisor/Mentor Signature (type names of each faculty advisor/mentor)

I (We) affirm that the signature above was completed by the person(s) named therein.