

## **Policy and Procedures for the Protection of Human Subjects in Research at Angelo State University**

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Executive Summary: This document outlines the current policies and procedures for institutional review of faculty research in accordance with current United States codes. The document describes the creation and structure of the Institutional Review Board (IRB), the responsibilities of members, the role of the IRB Chairperson, types of studies that the IRB may evaluate, and examples of system throughput depending on the type of research being evaluated.

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## TABLE OF CONTENTS

<b>SECTION 1 – COMPOSITION AND STRUCTURE OF THE IRB</b>	<b>3</b>
<hr/>	
JOB ROLES AND RESPONSIBILITIES	3
EXECUTIVE STRUCTURE	4
BOARD STRUCTURE	4
<b>SECTION 2 – CORE INSTITUTIONAL REVIEW PROCESSES</b>	<b>4</b>
<hr/>	
DEFINITION OF TERMS	4
SUBMISSION TYPES AND RULES	5
SUBMITTING RESEARCH TO THE IRB	7
SUBMISSION RULES	8
PROTOTYPICAL THROUGHPUT EXAMPLES	9
<b>SECTION 3 – ADDITIONAL POLICIES AND PROCEDURES</b>	<b>11</b>
<hr/>	
CONTINUING REVIEW OF ONGOING RESEARCH	11
DETERMINATION OF PROJECTS REQUIRING FREQUENT REVIEW	11
PROCEDURES FOR REVIEWING CHANGES IN AN APPROVED IRB PROTOCOL	12
POLICIES GOVERNING UNANTICIPATED ETHICAL VIOLATIONS OR CONCERNS	12
POLICIES GOVERNING FINDINGS OF NON-COMPLIANCE WITH IRB DETERMINATIONS	13

## **Section 1. Composition and Structure of the IRB.**

Angelo State University's Internal Review (IR) system operates through a faculty-led committee called the Institutional Review Board (IRB). Angelo State University's published policy statements indicate that the IRB and its processes are governed by the relevant sections of the Common Rule (45 CFR 46, Protection of Human Subjects, revised October 1, 2010). While 45 CFR 46 provides general regulations concerning institutional control of research, each institution has some freedom to design the flow of proposals through its system to maximize its expediency.

The core purpose of the IRB is to assess the ethicality and legality of research conducted by the host institution. While this may at times involve constructive criticism of the scientific theory and reasoning behind a study, the IRB *cannot* judge a proposed study negatively solely on theoretical disagreement with the researcher. The scientific merit of a study can be considered only as a component in an IRB deliberation if ethical, legal or moral principles are threatened by a specific scientific aspect of the study.

Angelo State University's IRB committee is composed of a small set of faculty members from colleges engaged in research activity. One faculty member acts as a chairperson and administrates the activities of the committee. The chairperson is the primary point of contact for all IRB submissions.

### *Job Roles and Responsibilities*

- **IRB Chairperson** – the chairperson performs the following duties:
  - receives submitted IRB documentation from researchers through the IRB Blackboard site (see below)
  - determines whether the research is exempt, expedited or requires full-board review (see below)
  - communicates with the researcher(s) in a timely manner about the status of their submission(s)
  - ensures that the interests of ASU and the ethical responsibilities of the researcher(s) are fully and completely satisfied in the appropriate IRB documentation
  - maintains and updates the university's IRB site on Blackboard
- **IRB Member** – the board member performs the following duties:
  - reviews IRB documentation as necessary when asked by the IRB chairperson to do so
  - conducts reviews in a timely manner and on the ethical merits of the research

### *Executive Structure*

The Provost's office maintains data on the current IRB members and is involved in the replacement of those members as is necessary. The Office of Sponsored Projects (OSP) exists directly under the Provost's office and also reports to the Dean of Graduate Studies. The OSP is responsible for supporting the mission of the IRB by providing guidance and assistance with ethical questions and keeping the IRB chairperson updated on current federal and state regulations that directly affect the work of the IRB.

### *Board Structure*

The Institutional Review Board is composed of no fewer than 5 members. Per United States Code, the membership is mostly made up of university faculty, with the exception of one member who is a layperson member of the community within which the university exists (usually labeled an "outside" member). There must be at least one (1) active IRB member from each of the following colleges at all times: the College of Health and Human Services and the College of Arts and Sciences. The chairperson may be from either college. IRB membership will always conform to pertinent federal regulations, specifically regarding the demographic diversity of the committee. Also, the outside member must not possess "primary concerns that are scientific" in nature and must not be related to anyone affiliated with the University. If the IRB chooses to consult with a non-member expert, this is allowable as long as the non-member expert does not vote.

IRB members serve for a three-year term and may continue membership beyond their first term, as long as the Provost's office approves their continued appointment. If a member chooses to leave the IRB, that individual must notify the IRB chairperson in writing by October 1 of the last academic year of service. If the IRB chairperson wishes to retire, that individual must identify, select and train the new IRB chairperson during the final academic year of service. The IRB chairperson **MUST** be selected from the current IRB membership, but a new IRB member may be selected from the faculty at large.

## **Section 2. Core Institutional Review Processes.**

### *Definitions of Terms*

The following definitions come from Title 45, Part 46, Section 102 of the *Code of Federal Regulations*, and they apply to all projects covered by this procedure.

**Human subject** means a living individual about whom an investigator (whether professional or student) conducting research obtains:

1. Data through intervention or interaction with the individual, or
2. Identifiable private information.

**Intervention** includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.

**Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

**Private information** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

**Research** means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

### *Submission Types and Rules*

There are three types of research studies that the IRB may review:

Exempt studies – these studies require only the review and approval of the IRB chairperson. This type of research makes up the majority of studies handled by the IRB.

**Note: ANY research that targets protected populations (children, inmates, pregnant women, and those mentally unable to offer informed consent) CANNOT be classified as exempt, regardless of the protocol involved.** The following criteria from 45 CFR 46.101 are used to identify a study as exempt:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
  - a. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
  - b. any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt above, if:
  - a. the human subjects are elected or appointed public officials or candidates for public office; or
  - b. federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
5. Research and demonstration projects that are conducted by or subject to the approval of department or agency heads, and that are designed to study, evaluate, or otherwise examine:
  - a. public benefit or service programs;
  - b. procedures for obtaining benefits or services under those programs;
  - c. possible changes in or alternatives to those programs or procedures; or
  - d. possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Expedited studies – these studies require review and approval by an *ad hoc* subset of the IRB, including the chairperson and 2 other IRB members. Pursuant to federal regulations, if the *ad hoc* committee recommends disapproval of the study, a full-board meeting of the IRB must be convened. The following criteria are used to identify a study as exempt:

- A. Research activities that present no more than minimal risk to human subjects;
- B. Research activities that do not place the participant at substantial risk should confidentiality be breached. These risks include:
  - a. criminal or civil liability;
  - b. financial loss;
  - c. loss of employability or insurability;
  - d. social stigma or loss of reputation;
- C. Research activities that are not connected to classified research.

By way of example, the criteria for expedited review include the following topic areas:

- A. Clinical drug and medical device studies (under certain conditions);
- B. Collection of blood samples (under certain conditions as outlined in federal regulations);
- C. Collection of biological specimens such as sputum, hair, saliva, skin cells, and placenta, by noninvasive means;
- D. Body measurement including MRIs, EEG/EKGs, strength testing and exercise, and sensory acuity tests;
- E. Voice, video, digital or image recording used for research purposes;
- F. Individual and group behavior (including but not limited to perception, cognition, motivation, identity, language, communication, cultural beliefs, and social behavior – methodologies include but are not limited to surveys, oral histories, focus groups, human factors analyses, program evaluation, and interviews).

Full-board review studies – these studies require review and approval by the entire IRB membership, utilizing an in-person meeting, a discussion, and a vote. Any proposal that cannot be classified according to the requirements for either exempt or expedited review must, by default, be classified as full-board review. Additionally, an expedited review process that leads to a decision to disapprove a study must be vetted by a full board review process. The University will comply with all federal regulations concerning the composition, quorum, and voting protocol rules when convening a full board review.

### *Submitting Research to the IRB*

Angelo State University uses an online submission protocol hosted on the university's Blackboard course management system. The ASU IRB has an "organization" identity on Blackboard, and all faculty members are automatically enrolled as participants. All IRB board members are enrolled as "instructors" so that any board member may log into the site and view proposals at any time. All relevant forms are located on the Blackboard site, including the proposal form and the consent form templates. A link to the online ethics training program is also provided there. Finally, rules for the preparation of the proposal and consent documents are located on the IRB Blackboard site.

The current IRB submission process is as follows:

1. The faculty member in charge of the study (the Principal Investigator, or "PI") must access the Blackboard IRB site and upload both the completed proposal form and the completed consent form.
2. The IRB chairperson is notified via email that an IRB submission has been completed.
3. The chairperson will access the Blackboard site and view the appropriate documentation. At this point, the IRB chairperson will evaluate the submitted project and classify it as "exempt," "expedited," or "full-board." If the IRB chairperson has a conflict of interest regarding the study, the chairperson will authorize an IRB committee member to act on his/her behalf.
4. The project will then move through the IRB system in the prescribed manner, depending on the classification of the study.
5. Once review is complete, the IRB chairperson notifies the PI of the decision through the Blackboard site. A score of "1" indicates that the approval has been granted. Any score less than "1" indicates that revisions are required before IRB approval is possible. Comments may also be sent to the PI at this time, describing specific revisions.
6. If revisions are necessary, the PI will upload a new version of the affected documentation through the IRB Blackboard site, and the review process begins again.

The review process may be of indeterminate length, but the mission of the IRB is to make every review as timely and thorough as possible. Therefore, most "exempt" studies will pass through review within one to two weeks of submission, and most "expedited" studies will pass through review within three to four weeks of submission. Full-board reviews will take longer because the IRB will address "full-board" studies only once a semester, because of the need for an in-person review meeting.

### *Submission Rules*

- 1) All required ASU forms must be completed in full and the electronic signatures must be complete.
- 2) All programmatic research proposals must cover no more than a 3-year time period before resubmission is necessary.
- 3) Submission summaries must be no more than 5 pages in length (10 pages are allowable for studies that will trigger full-board review).
- 4) Submissions must be in PDF format – no exceptions.
- 5) Submissions must be delivered to the IRB Chairperson via the IRB Blackboard site – NO PAPER COPIES WILL BE ACCEPTED.
- 6) Submissions will be accepted year-round.

### *Prototypical Throughput Examples*

#### Case 1: Exempt Proposal

- 1) Proposal forms submitted according to submission guidelines to IRB Blackboard site
- 2) IRB chairperson confirms exempt status and reviews project
- 3) PI is contacted through Blackboard with IRB decision and stamped consent forms are mailed to the PI via interoffice mail
- 4) **Target time from submission to decision: 2-3 weeks**

#### Case 2: Expedited Proposal

- 1) Proposal forms submitted according to submission guidelines to IRB Blackboard site
- 2) IRB chairperson confirms that exempt status is not applicable -- checks content for possible expedited review
- 3) Expedited review is confirmed; Chairperson assigns proposal to ad hoc reviewers (AHRs) within 5 days of receipt
- 4) AHRs review and make determination on proposal
- 5) AHRs send decision with necessary support to IRB chairperson within two weeks of receipt
- 6) IRB chairperson enters score into Blackboard and contacts PI with decision and appropriate commentary
- 7) If decision is to approve with or without minor revision:
  - a. IRB chairperson sends stamped consent forms to PI via interoffice mail
  - b. **Target time from submission to decision: 3-4 weeks**
- 8) If decision is to require substantial revisions:
  - a. IRB chairperson contacts PI with required edits and changes
  - b. Proposal status is placed on “hold” until PI acts

- c. If the proposal is revised and returned, the IRB chairperson may act as a proxy for the AHR committee to review those changes for adequacy
- d. Process loops back to Steps #7 and #8

9) **Target time from submission to decision: 1-2 weeks per revision**

Case 3: Full-Board Proposal (Note: Full-board meetings may be held once annually at the scheduling discretion of the IRB chairperson, with or without a precipitating submission to be reviewed.)

- 1) Proposal forms submitted according to submission guidelines to IRB chairperson
- 2) IRB chairperson conducts initial review of documentation:
  - a. Exempt status is not confirmed; IRB chair checks content for possible expedited review
  - b. Expedited review is not confirmed; Chairperson acts as chair of full board meeting and adds item to agenda
  - c. Full board meeting will be held once at the end of each semester to review identified projects
- 3) Full board reviews and makes determination on proposal
- 4) Chairperson sends decision with necessary support through Blackboard to PI within 5 days of board meeting
- 5) If decision is to approve with or without minor revision:
  - a. PI receives stamped consent forms via interoffice mail
  - b. **Target time from submission to decision: 4-6 weeks**
- 6) If decision is to require substantial revisions:
  - a. PI receives detailed information about required changes to protocols through the Blackboard site
  - b. Proposal status is placed on “hold” until PI acts
  - c. If the proposal is revised and returned, the IRB chairperson must convene an AHR committee to review the new changes within 5 days of receipt
  - d. AHR committee reviews project and renders decision within 10 days of receipt
  - e. Process loops back to Steps #5 and #6
- 7) **Target time from submission to decision: 4-6 weeks for first system cycle, 1-2 weeks per revision**

\* Note: this timeline depends on the timing of the scheduled IRB meeting

Case 4: Request for Continuation of Programmatic Research

- 1) Continuation forms submitted according to submission guidelines to IRB chairperson
  - a. Note: original proposal must also be sent to Chairperson at this time
- 2) Chairperson receives proposal and checks content against original proposal to check for major changes or other concerns
- 3) Chairperson sends decision on continuation to PI within 1-2 weeks of receipt

- 4) If decision is to approve with or without minor revision:
  - a. PI will receive stamped consent forms via interoffice mail
  - b. **Target time from submission to decision: 1-2 weeks**
- 5) If decision is to require substantial revisions:
  - a. Proposal is returned to PI with instructions to revise
  - b. Proposal status is placed on “hold” until PI acts
  - c. If the proposal is revised and returned, the chairperson will review the documentation within 3 days of receipt
  - d. Process loops back to Steps #4 and #5
- 6) **Target time from submission to decision: 1-2 weeks per revision**

*In sum, the following structure and process, considering that most proposals will either be Exempt or Expedited status, is intended to produce an average delay time from submission to decision of approximately **3-4 weeks**. In addition, this process spreads the administrative workload over the entire committee, adds important administrative support from the OSP, and enhances communication between the IR system and investigators.*

### **Section 3: Additional Policies and Procedures Concerning IRB Activities**

#### *Continuing Reviews of Ongoing Research*

Researchers who wish to request approval for a study that is not completed by the expiration of the original IRB approval must submit an IRB Continuing Research Addendum to the IRB committee by the expiration date of the original approval. Additionally, researchers must indicate on the original IRB submission that they anticipate the study will progress beyond the standard 12-month lifespan of an IRB approval. Continuing research reviews will be handled in the same manner as the original review.

Continuing review is NOT an acceptable vehicle if any of the following conditions exist:

- 1) The study has changed its methodology, participant pool, dissemination expectations, and/or funding sources;
- 2) The study has been determined to have changed classifications (i.e., from exempt to expedited)

#### *Determination of Projects Requiring Frequent Review*

Studies that may require more frequent review by the IRB will be initially identified by the IRB chairperson. This determination must be verified and supported by the full IRB committee.

Researchers will be notified during the IRB review process that their study has been marked as “frequent review.” The number of reviews and the time period between

those reviews will be determined by the IRB committee and communicated to the researchers, along with a justification of the committee's decision.

Researchers are responsible for completing the requisite documentation for each review, which will be customized by the IRB chairperson to fit the specific characteristics of the study in question. The IRB will NOT initiate contact with the researcher for these reviews.

#### *Procedures for Amending an Approved IRB Protocol*

NOTE: The procedures in this subsection refer only to changes in the following aspects of a study:

- 1) Significant alteration in the study's methodology. "Significant alteration" is usually defined as an alteration that will change the participant's experience in the study in a way that may impact perceptions of ethicality, legality and risk exposure. For example, if a researcher is using a pencil-and-paper questionnaire and decides to convert that questionnaire to a computerized version, doing so would NOT require IRB approval.
- 2) Significant alteration in the participant population targeted. This could include identification of the population, recruitment, and/or compensation. *If the participant pool changes to include a protected population under federal regulations, a NEW IRB SUBMISSION must be completed.* For example, if the researcher wishes to change from adults to children, the policies in this subsection DO NOT apply.
- 3) Significant alteration in funding sources. If a research project has been approved by the IRB and a funding source begins to support the research during this approval period that was NOT identified on the original form, the IRB must be notified of this change BEFORE FUNDING MAY BEGIN.
- 4) Significant changes in dissemination expectations. While this is a rare occurrence, it is possible that a researcher may wish to use the data collected in the study in such a manner that raises ethical concerns. Thus, any changes in expected dissemination must be reported to the IRB.
- 5) Any other significant changes that affect the participation of human subjects, including changes to informed consent and/or assent forms, modifying or adding sites for conducting the research, changes in the Principal Investigator or key personnel, and unanticipated risks to the participants.

The researcher is responsible for submitting the appropriate document(s) into the IRB system to request approval of significant changes. If it is determined that significant changes have been implemented in the study BEFORE the IRB was aware, *approval for the study will be immediately revoked and the researcher will be restricted from completing the study.* Additionally, disciplinary action may result.

### *Policies Governing Unanticipated Ethical Violations or Concerns*

Recognizing that it is not possible to foresee all potential ethical or legal risks to participants, it is necessary to have a procedure in place to allow for researchers to communicate with the IRB when unanticipated problems arise.

If such a situation occurs, the researcher must report the full details of the situation to the IRB *in the most timely manner possible*. The IRB will require a full report of the incident, including a full narrative with background information and how the incident may have created an ethical concern or violation. Once this report is submitted, it is the researcher's responsibility to *immediately suspend all research activity on the affected project until otherwise informed by the IRB and/or university officials*.

The IRB will consider the submitted report in a full-board session, to be convened in as timely a manner as possible. In addition, the IRB chairperson will notify the appropriate university officials of the initiation of the investigation and its status as it progresses. Based on the results of this deliberation, the IRB may decide in one of the following ways:

- 1) The incident as reported DOES NOT constitute an ethical violation or concern;
- 2) The incident as reported MAY constitute an ethical violation or concern, but more information is needed;
- 3) The incident as reported DOES constitute an ethical violation or concern and immediate rectification of this condition is warranted.

### *Policies Governing Findings of Non-Compliance with IRB Determinations*

The IRB reserves the power to terminate with immediate effect any research project that specifically violates the ethical guidelines set by the IRB for the conduct of said project. This includes intentional and unintentional violations, as well as short-term and pervasive violations. If the IRB has evidence of such malfeasance, communication will be sent to the researcher with instructions to terminate the research project. It will also include information about how a formal inquiry into the suspected malfeasance will ensue. Formal inquiries may take different forms depending on the nature of the specific situation. These inquiries will be constructed by the IRB chairperson and must be approved by appropriate university administration before they can begin. Additionally, any such violations that also constitute possible charges of misconduct in research will be handled in accordance with ASU OP 56.02, "Misconduct in Research."

Any unanticipated problems, serious findings of non-compliance, and/or termination of IRB approvals will be reported to the U.S. Department of Health and Human Services Office of Human Research Protections and/or to the funding agency (in the case of sponsored research) in accordance with federal statute and the terms and conditions of the sponsoring agency.