Introduction

West Texas A&M University (hereafter referred to as “the University”) recognizes the need for investigations in which human beings may serve as research subjects. The University is also cognizant of its responsibility for ensuring that the privacy, safety, health, and welfare of such subjects are adequately protected. The University has thus established an Institutional Review Board (hereafter referred to as
“IRB”) to review and approve the adequacy of human subject protection. The University has assured federal regulatory agencies that the institution will review and approve all research involving human subjects, regardless of funding source, before it is initiated.

Purpose

This procedure describes the procedures relating to HHS regulation 45 CFR 46.103(b)(4) and (5) the procedures which the IRB will follow for conducting its initial review of research. This procedure is intended to enhance human subject protection, the quality of research data and education of faculty, staff, and students involved in the conduct of human subjects research and the individuals involved in the ethics and compliance activities related to such research, including IRB members and staff.

PART I

Initial Review of Research

The IRB will determine the review status of the submitted protocol.

Criteria for IRB Approval of Research

In order to approve research covered by this procedure the IRB shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such
as children, prisoners, pregnant women, mentally disabled persons, or economically disadvantaged persons.

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative.

5. Informed consent will be appropriately documented.

6. When appropriate, the research plan makes adequate provision for monitoring the data collected in order to ensure the safety of subjects.

7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

8. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Initial Review of Programs

1. The prospective principal investigator will submit to the Chair of the IRB one email-attached copy of the completed IRB proposal cover sheet, synopsis of procedures, assessment instruments, and any treatment intervention protocols, together with a specimen statement of informed consent.

2. All proposals for research shall be submitted to the full membership of the IRB. For certain specified forms of research (Part I, Section A, Paragraph 4), an expedited review shall be conducted. Any member of the IRB may request a full review of the proposal.

3. The IRB is expected to complete its initial action on the protocol within three weeks after submission to the IRB by the principal investigator. In those exceptional instances when a review is not completed prior to the submission of the proposal to a potential sponsor, the review action must be completed within three weeks following the submission date.

4. Only the Chair of the IRB, or his/her authorized representative, will notify the principal investigator of the IRB's decision. The principal investigator must be available to the IRB to discuss the protocol or consent forms if necessary. It will not be sufficient for the IRB to discuss the protocol with a research associate, a research assistant, or another representative of the principal investigator.

5. The IRB may take one of three actions in regard to the proposed protocol and consent forms. The proposed protocol and consent forms may be: (i) approved, (ii) approved conditionally, or (iii) disapproved. The action to conditionally approve a protocol should be taken in cases in which the IRB is unable to satisfy its concerns regarding the rights and well-being of the subjects. In the event that a protocol is conditionally approved, the principal investigator must be notified
immediately regarding both that action and the reason for the action in order that he/she has sufficient time to supply members of the IRB with any needed additional information prior to the next scheduled meeting of the IRB. Procedures involving human subjects may not proceed without final approval from the IRB.

6. Protocols that have been approved by another IRB will be submitted to the committee for review in its approved format.

Disposition and Distribution of Reviewed Materials

The procedure for disapproved protocols is as follows: if the proposed protocol is disapproved, the principal investigator will be informed in writing of the reasons for disapproval by the Chair of the IRB. Every effort shall be made by the IRB and the principal investigator to resolve those elements of the protocol which make it unacceptable. The principal investigator may then submit a revised protocol which will be reviewed as above.

Notice of IRB Action

Written notice of the decision shall be sent by the Chair of the IRB to the principal investigator of his/her proposal.

Subject's Rights and Grievances

The subject should be informed as to the extent he/she will be able to:

1. Consider carefully the decision to participate in research.
2. Ask questions freely.
3. Recognize that he/she is free to withdraw from participation at any time.
4. Notify the investigator promptly of adverse effects of participation and;
5. Take unresolved grievances about participation in the research to the IRB chair or the Vice President for Research and Compliance. In consultation with the Vice President for Research and Compliance, the IRB chair will determine whether the complaint is an issue of research misconduct or potential non-compliance in the course of human subjects research. An investigation will be initiated pursuant to WTAMU SOP No. 15.99.03.W1.04AR, Ethics in Research, Scholarship and Creative Work: Research Misconduct or WTAMU SOP No. 15.99.03.W1.05AR, Potential Non-Compliance in the Course of Human Subjects Research as appropriate.
If the issue is not applicable to Ethics in Research, Scholarship and Creative Work: Research Misconduct or potential Non-Compliance in the Course of Human Subjects Research, it may be referred to the associated college administration from which the PI or PIs reside.

Suspension or Termination of Research by the Institutional Review Board

The IRB has the authority to suspend or terminate approval of any research involving human subjects conducted at, or sponsored by, the University that is not being conducted in accordance with the University's policies and procedures (SOP No. 15.99.05.W1.05AR Potential Non-Compliance in the Course of Human Subjects) or with the IRB's requirements or that has been associated with unexpected harm to the subjects. Any suspension or termination of approval will include a statement of the reasons for the action of the IRB and shall be reported promptly to the investigator and appropriate institutional officials. For any U.S. Department of Health and Human Services supported work so terminated, U.S. Department of Health and Human Services regulations require that the Secretary of Health and Human Services be notified as well.

PART II

DISTRIBUTION OF RESPONSIBILITY

The responsibility for the protection of subjects in research is distributed among several parties: investigator, head of the department, dean of the college, the IRB, the University administration, sponsoring agencies, the subjects themselves, and those who control access to subjects.

Principal Investigator

The primary responsibility for the day-to-day assurance for protection of the rights and welfare of human subjects lies with the individual responsible for the conduct of the activity, i.e., the principal investigator. Specifically, the principal investigator is responsible for the following:

1. Careful research design;

2. Careful adherence to ethical codes and applicable policies and procedures of the University, sponsoring agency, and cooperating institutions, if any;

3. Training and supervision of all co-investigators, staff and, students who are participating in research;

4. Providing required information and taking all steps in the initial and continuing review of research;

5. Retaining required records for a minimum of three years following the completion of the research project;
6. Obtaining prior approval of the IRB for changes in a research activity; and

7. Prompt reporting to the IRB of unanticipated problems that involve risks to subjects or others.

**Head of the Department and Dean of the College**

The Head of the Department and the Dean of the College have the responsibility to:

1. Assure that faculty, staff, and students are kept informed of the University policy and procedures and of their responsibilities for protecting the rights and welfare of human subjects involved in research;

2. Report promptly to the IRB any unanticipated problems involving risks to subjects or others.

**Institutional Review Board**

The IRB, which functions under authority delegated by the President of the University, serves as the primary focus of institutional authority and responsibility for monitoring and approving all activities involving the use of human subjects. Its responsibilities include the following:

1. Implementation of approved policies and the development of procedures for proper review of such activities.

2. Ascertaining acceptability of proposed research in terms of institutional commitments, applicable law, and standards of professional conduct and practice.

3. Development of information, instructions, and advice for investigators, reviewers, and research subjects.

4. Development of procedures for the initial and continuing review of such activities.

5. Documentation of review and the maintenance of records of such activities in conformity with applicable law, regulations, and policies.

6. Investigate if problems relating to human rights which arise out of the research activities.

7. Assuring compliance with externally imposed policies and regulations regarding human rights.

8. Reporting to the appropriate institutional officials and, for research funded by the U.S. Department of Health and Human Services, to the Secretary of Health and Human Services, any serious or continuing noncompliance by investigators with the requirements and determination of the IRB.

**Institutional Review Board Records**

1. The IRB shall prepare and maintain adequate documentation of activities including the following:

   (a) Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals,
approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(b) Minutes of IRB meetings, which shall be in sufficient detail to document attendance at the meetings; actions taken by the IRB; the vote on those actions, including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

(c) Records of continuing review activities.

(d) Copies of all correspondence between the IRB and the investigators.

(e) A list of IRB members.

(f) Written procedures for the IRB.

(g) Statements of significant new findings that are provided to subjects.

2. The records required by this regulation shall be retained for at least three years after completion of the research, and the records shall be accessible for inspection and copying.

3. All of the information required by this section of this document shall be filed at the Killgore Research Center by the Chair of the IRB within one month of the date of final approval of the research.

---

**Related Statutes, Policies, or Requirements**

45 C.F.R., Part 46
21 C.F.R., Parts 50, 56, 312 and 812
Belmont Report
Texas Government Code, Chapter 552

*System Regulation 15.99.01 – Use of Human Participants in Research*

---

**Contact Office**

Office of Research
Institutional Review Board of Human Subjects
(806) 651-2270