ACADEMIC RESEARCH ENVIRONMENTAL HEALTH AND SAFETY
STANDARD OPERATING PROCEDURES

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Supplements TAMUS Regulation 15.99.05
PART I

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.

Based on United States Department of Health and Human Services (HHS) regulations at 45 CFR 46.103(b)(4) and (5) require that institutions have written IRB procedures for each of the following:

1. the procedures which the IRB will follow for conducting its initial review of research; See SOP 15.99.05.W1.08AR Institutional Review Board for Human Subjects – Initial Review of Research Procedure

2. the procedures which the IRB will follow for conducting its continuing review of research; See SOP 15.99.05.W1.09AR Institutional Review Board for Human Subjects – Continuing Review of Research Procedure

3. the procedures which the IRB will follow for reporting its findings and actions to investigators and the institution; See SOP 15.99.05.W1.05AR Potential Non-Compliance in the Course of Human Subjects Research

4. the procedures which the IRB will follow for determining which projects require review more often than annually; See SOP 15.99.05.W1.12AR Institutional Review Board for Human Subjects – Determining Which Projects Require More Often Than Annually Procedure

5. the procedures which the IRB will follow for determining which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; See SOP 15.99.05.W1.11AR Institutional Review Board for Human Subjects – Post Approval Monitoring Procedure

6. the procedures which the IRB will follow for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved
research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject; and See SOP 15.99.05.W1.10AR Institutional Review Board for Human Subjects – Amendment of Research Procedure

(7) the procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, any Department or Agency head, and OHRP of:

(a) any unanticipated problems involving risks to subjects or others (hereinafter referred to as unanticipated problems);

(b) any serious or continuing noncompliance with 45 CFR Part 46 or the requirements or determinations of the IRB; and

(c) any suspension or termination of IRB approval.

See SOP 15.99.05.W1.13AR Institutional Review Board for Human Subjects – Unanticipated Problems & Serious Adverse Events

The policies of the University with respect to research, development, and related activities are based on the following principals:

All research programs which involve human subjects must be reviewed by, and receive the approval of, the IRB prior to initiation of the protocol. Continuing research programs are subject to review. This review must comply with the elements of informed consent (Appendix V).

Participation of a human subject in any experiment must be voluntary and the information provided to gain subjects' consents must comply with the elements of informed consent (Appendix V).

The risks to the subject must be acceptable when measured against possible benefit to him/her or by the importance of the knowledge to be gained as a result of participation.

Research and training activities involving human subjects must be supervised by qualified persons.
Research activities in which the only involvement of human subjects will be in one or more of the following categories are subject to exempt review under these regulations unless the research is covered by other subparts of this part:

(a) 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.

(b) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) 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; and/or (iii) the research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.

(c) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph I.A.5. of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(d) 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.

(e) Research and demonstration projects designed to study, evaluate, or otherwise examine the following: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to, those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
(f) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) 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 review procedures may be used for certain kinds of research involving no more than minimal risk, and for minor changes in approved research. The list of categories of research that may be reviewed by the IRB through an expedited review procedure include:

(a) Clinical studies of drugs and medical devices only when condition (1) or (2) is met.

(1). Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(2). Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

(b) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(1). from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(2). from other adults and children\(^2\), considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

(c) Prospective collection of biological specimens for research purposes by noninvasive means.
Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncanulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

(d) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject’s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(e) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
(f) Collection of data from voice, video, digital, or image recordings made for research purposes.

(g) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

(h) Continuing review of research previously approved by the convened IRB as follows:

(1). where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(2). where no subjects have been enrolled and no additional risks have been identified; or

(3). where the remaining research activities are limited to data analysis.

i. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Simple surveys conducted by the University and its colleges, divisions, or departments for the purpose of program evaluation or institutional effectiveness and surveys conducted by students as a single course assignment under the supervision of the course instructor are subject to exemption from IRB approval provided that (Appendix IV):

(a) The survey sample does not include children under the age of eighteen; mentally disabled persons; institutionalized elderly; economically or educationally disadvantaged persons; or persons with limited civil freedoms such, as prisoners or persons subject to military discipline.
(b) The survey does not require disclosure of illegal conduct, drug use, sexual behavior, sexually transmitted diseases, or use of alcohol.
(c) Survey responses would not place the subject at risk of criminal or civil liability or be damaging to the subject’s financial standing or employability.
(d) Participation is voluntary and confidentiality is preserved.
(e) A written statement accompanies the survey informing subjects of the purpose of the survey, how the investigator may be contacted, that participation is voluntary without reward or penalty, that they may ask questions or withdraw at any time, and that confidentiality will be maintained.

The policies contained herein are based upon the following:

(a) Nuremberg Code
(b) Declaration of Helsinki
(c) National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, "The Belmont Report," U.S. Public Health Service
(d) American Psychological Association Ethical Guidelines
(e) Code of Federal Regulations Title 45, Protection of Human Subjects Act, Sections 46.101-46.409

**Definition of Terms**

**Research**

“Research” means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to general 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.

**Human Subject**

“Human subject” means a living individual 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. “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. “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.

The definition of “subject” excludes all accepted and established service relationships, such as the normal relationship of patients to physicians, students to professors, and other clients to professionals in which the patient, student, or client is receiving aid or services consistent with accepted and established practice, and intended only to meet his/her own personal needs. The professional-client relationship has the welfare of the client as the primary objective, whereas the investigator-subject relationship has the discovery of new knowledge as its primary objective. This difference may not be fully understood by the subject who is also a client and can result in the investigator's gaining consent without free decision, in part due to a trust based on a presumed role which the investigator is not necessarily fulfilling at that time.

The normal employer-employee relationship, in which legitimate services are rendered for salary, wages, or remuneration in keeping with customary written or verbal contracts, is also excluded from the definition of subject. Payment of subjects does not alter their status as subjects.

If doubt exists as to whether the procedures to be employed are within accepted and established practice or whether the purpose is only for the personal needs of the client, the activity should be considered to involve subjects whose rights and welfare are to be protected in accord with this policy statement. Similarly, if doubt exists as to whether the procedures are within the normal limits of the employee's work scope, employees should
be considered to be participating as human subjects, and their rights and welfare must be protected.

**Special Classes of Subjects**

There are special classes of subjects for which additional protections pertaining to research are required. These are as follows:

(a) Pregnant women and fetuses  
(b) Prisoners  
(c) Children under the age of 18

See Appendix II for additional rules related to these classes of subjects.

**Risk**

(a) Risk - An individual is considered to be “at risk” if he/she may be exposed to the possibility of physical, psychological, sociological, or other harm as a consequence of participation as a subject in research, development, or related activities. The determination of individual risk is a matter of the application of common sense and sound professional judgment to the circumstances of the activity in question. Responsibility for this determination resides at all levels of the University review process, including the investigator.  
(b) Minimal Risk - “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.

**Statement of Policy**

The University affirms the need for academic freedom, accompanied by an equally demanding concept of responsibility, and the value of well-designed, responsible activities in the conduct of authorized research involving human subjects.

Recognizing its basic responsibility to assure the protection of human subjects involved in research activities, the University has adopted the following statement of policy.
Adherence to Published Codes, Policies, and Procedures

Investigations conducted at or sponsored by the University shall:

(a) Adhere to the Belmont Principals.
(b) Comply with the Nuremberg Code, or a published ethical code developed on the principles of the Nuremberg Code by a recognized professional association and approved by the IRB.
(c) Comply with the Declaration of Helsinki.
(d) Comply with guidelines of the American Psychological Association.
(e) Adhere to the policies and procedures set forth in this document in addition to those published in the West Texas A&M University Faculty Handbook.

Selection of Subjects

Selection of subjects must be 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 or educationally disadvantaged persons. Such groups should be fully protected against the danger of being involved in research solely for administrative convenience or because they are easy to manipulate as a result of their dependent status.

The principal of justice requires that there be fair procedures and outcomes in the selection of research subjects. For example, individual justice dictates that subjects should not be selected for potentially beneficial research on the basis of favoritism. Nor should risky research be restricted to subjects who are powerless. Social justice requires recognition of differences among groups in ability to bear burdens, gives an order of preference in the selection of kinds of subjects (for example, adults before children), and dictates that some kinds of persons (for example, institutionalized mentally infirm persons or prisoners) may be involved as research subjects only on certain conditions.

The methods used for approaching subjects and securing their participation shall be carefully designed to protect the privacy of the subjects and shall be reasonable in terms of the subjects condition or circumstances.
No coercion, explicit or implicit, shall be used to obtain or maintain cooperation. When the professional-client or faculty-student relationship is converted into an investigator-subject relationship, special care must be taken to assure that the subject feels completely free to decline to participate. When access to subjects is gained through cooperating institutions or individuals, care shall be taken not to abridge prior commitments made to the subjects about the confidentiality or other terms of the primary relationship.

**Privacy of Subjects and Confidentiality of Information**

Adequate provision must be made to protect the privacy of subjects and to maintain the confidentiality of identifiable information. Confidentiality provisions must meet reasonable standards for protection of privacy and comply with all applicable laws. Identifiable information shall not be disclosed outside the research group unless the subjects expressly agree otherwise in writing.

(a) The identity of subjects must not be released except with their expressed written permission.

(b) Use of stored data or information which was originally obtained for different purposes and which involves identifiable subjects, requires examination of the risk involved, determination of whether the new use is within the scope of the original consent or whether obtaining additional consent is necessary and feasible, and provision for the preservation of anonymity of the subjects.

Data that are part of the public domain under applicable federal or state law are not covered by the foregoing restrictions.

**Requirement for Voluntary Participation**

Participation of human beings as subjects in research governed by this policy must be voluntary, i.e., participation must occur as the result of free choice without compulsion or obligation.

The principal of voluntary participation of subjects applies whether or not the research is governed by federal regulations and whether or not the research is subject to prior review.

Both the rights of individuals to be protected against injury or invasion of their privacy and their interests as members of a free society in preserving their dignity are recognized
as major concerns and must be protected. Therefore, research involving human subjects may be undertaken only with the voluntary written or verbal consent of the subject or, if the subject lacks the capacity to consent, with the written consent of his/her legally authorized representatives.

When pregnant women, fetuses, minors, or prisoners are subjects in research, special care must be taken to assure that consent for participation is obtained in accordance with applicable rules and regulations (Appendix II).

**Requirement of Informed Consent**

(a) Informed Consent

The informed consent of subjects will be obtained by methods that are adequate and appropriate. "Informed consent" is the knowing consent from an individual, or his/her legally authorized representative, who is so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion. It is very important that the subject be fully informed as to what is expected of his/her involvement in the project.

Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights or releases or appears to release the investigator, the sponsoring institution, or its agents from liability for negligence.

(b) Methods and Considerations
Consent must be obtained from the subjects themselves with certain allowable exceptions: When the subjects are not legally or physically capable of giving informed consent because of age, mental incapacity, or inability to communicate, the consent may be signed by the subject’s legally authorized representative. In this kind of investigation, the IRB and the investigator will be required to exercise the highest degree of discernment and judgment of the risk/benefit relationship. Careful consideration should be given not only to the legally authorized representative’s depth of interest and concern with the subject’s rights and welfare, but also to whether the third parties are authorized to expose the subjects to the risks involved. A parent, for example, may have no authority to expose his/her child (for purposes of these guidelines, a minor child is defined as being younger than 18 years of age) to risk, except for the child's own benefit.

The IRB should determine whether the consent, either secured as a written document or given verbally, or if implicit in voluntary participation in a well-advertised activity, is adequate in the light of the risks to the subject, and the circumstances of the research. The IRB should also determine whether the information to be given to the subject or to the legal representative, orally or in writing, is a fair explanation of the procedure, its possible benefits, and its attendant hazards. In addition, the language used should be clear and unambiguous with every attempt to eliminate technical terms and jargon. When debriefing procedures are considered as a necessary part of the research plan, the IRB should ascertain that these will be complete and prompt. When a generalized form of consent is typically used, the IRB shall determine whether these routine procedures provide an adequate basis for the subject's informed consent to the particular procedures involved.

Adequate standards for informed consent must be satisfied. In addition to voluntariness as described above, disclosure and comprehension are essential elements of the consent process.

Disclosure includes the following:

i. the research procedures, their purposes, risks, and anticipated benefits;

ii. alternative procedures where therapy is involved; and
iii. a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research. The extent and nature of information shall be such that persons, knowing that the procedures are neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furtherance of knowledge. Even when some direct benefit to them is anticipated, subjects shall understand clearly the range of risk and the voluntary nature of participation.

In some research, fully informing the subject would invalidate the research. In such cases, it may be necessary to withhold information from the subject. However, information shall not be withheld if withholding it would affect a reasonable person's decision to participate or damage his/her subsequent self-esteem or health. Information about risks shall never be withheld for the purpose of eliciting the cooperation of subjects, and truthful answers shall always be given to direct questions about the research.

Research involving incomplete disclosure must have prior written approval of the IRB and is justified only if it is clear that:

i. incomplete disclosure is truly necessary to accomplish the goals of the research.

ii. there are no undisclosed risks to subjects that are more than minimal, and

iii. where appropriate, there is an adequate plan for debriefing subjects and disseminating research results to them.

Care shall be taken to distinguish cases in which disclosure would destroy or invalidate the research from cases in which disclosure would simply inconvenience the investigator.

Comprehension is the second essential element in informed consent. The manner and context in which information is conveyed is as important as the information itself. Consideration must be given to the subject's ability to understand the language and terminology used, as well as to the subject's physical and mental state. Investigators are responsible for ascertaining in writing that the subject has comprehended the information.
It shall be the responsibility of the principal investigator to make certain that the potential subjects in the research understand that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Additional details regarding the consent process and the requirements for documentation of consent are given in Appendix V.

**Implementation of Standard**

Sufficient information should be provided to each subject, and to the parent or guardian in the case of a minor child or to a responsible third party in the case of an incapacitated or infirm subject, prior to the investigation to permit obtaining informed consent to participate. For adult subjects, it is highly recommended that an oral briefing be provided by the principal investigator or by a fully-informed assistant, as to the general purpose of the research and as to the general procedures followed. An oral briefing, while highly recommended, is not required in all cases. However, in all experiments judged by the IRB to involve possibility of injury, subjects must sign a consent form (Appendix IV) following an oral briefing and prior to participating in the research project. The form selected should best meet the requirements of the proposed study. In the case of minor children or incapacitated or infirm subjects, it is necessary that the parents, guardians, or other responsible parties be given a briefing in written or oral form prior to the investigation in order to obtain their consent. As indicated on all forms, the subject must be given an opportunity to decline to participate or to terminate participation without prejudice even if the parent, guardian, or other responsible party has signed a consent form.

When prisoners or persons from the vulnerable groups described above are subjects of research, it is recommended that a signature be obtained from at least one person, not associated with the research, who has witnessed the signing of the consent form.
If none of the designated forms satisfy the needs of the proposed study, a special form may be designed. The form, however, must cover all items covered in Appendix V, Part A.

**Informing Subjects About the Research**

It is recognized that in some research it is not possible to fully inform the subject of the experimental procedures without destroying the validity of the research. For example, in a study of incidental learning, one cannot inform the subject that he/she will be tested for the retention of incidental rather than of task relevant information without biasing the subject's behavior in the original learning sessions.

Thus, while it is recognized that informed consent need not be based on full pre-participation information, it is the responsibility of the IRB to set limits to the incompleteness of such information. Further, in those studies in which it is proposed to mislead the subjects during data collection, the IRB has the responsibility of assessing whether this violates the rights or welfare of subjects, and if such violation exists the IRB must set limits for such studies.

Finally, in the event that the subjects are misled or deceived during data collection when they are participating as part of a learning experience connected with a course or program of study, it is particularly important to insure that the debriefing includes both a detailed description of the deception and a description of its need and the role it played within the experiment.

**Requirement of Documentation of Informed Consent**

(1) Informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(2) The consent form may be either of the following:

   i. A written consent document that embodies the elements of informed consent required by the IRB. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or
ii. A "short form" written consent document which states that the elements of informed consent required by the IRB have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person who actually obtains consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

The preference is for a written consent document signed by each subject or the legally-authorized representative.

(3) The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if the IRB finds either:

i. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked if the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

ii. That the research presents no more than minimal risk or harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

(4) In addition, the agreement, written or verbal (two witnesses are required for verbal consent), entered into by the subject, should include no exculpatory language through which the subject is made to waive, or to appear to waive, any of his/her legal rights, including any release of the University or its agents from liability for negligence.

(5) A copy of the consent form shall be given to the person signing the form.
(6) A copy of the form used as documentary evidence of informed consent must be retained in the files of the investigator for a period of three years and shall be made available to the IRB upon request.

**Limitation on Risk Involved**

As far as is possible, all risks shall be anticipated and carefully documented in advance. Proper precautions shall be taken and plans made to deal with emergencies that may develop in the course of even seemingly routine activities.

**Prior Review by the Institutional Review Board**

Human subject research that is conducted at or sponsored by the University, and that is pertinent to the policies and procedures contained in this document, must be submitted to the IRB for prior review and timely periodic review after approval. Changes in approved research may not be initiated without prior review and written approval of the IRB.

**Emergencies**

In the event of emergencies that may arise in the course of University research involving human subjects, the principal investigator or participants in the research are to contact 911, and/or the nearest medical facility (on campus University Police, 651-2300, and/or BSA Health Clinic, 655-2104). The individual should state the location and nature of emergency and inform the person to whom they are speaking of the relationship of the emergency to the research activity and give the principal investigator's name and telephone number.

The principal investigator is responsible for promptly reporting any such event to the Department Head, Dean of the College, and the Chair of the IRB.

All of the provisions of the "West Texas A&M University Accident Prevention Program" shall serve as guidelines when appropriate.
PART II

Procedures For Review

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 policy 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,
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

Please see SOP 15.99.05.W1.08AR Institutional Review Board for Human Subjects – Initial Review of Research Procedure

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.

Interim Review Procedures

Annual Closeout/Amendment/Continuation

If all data collection has been captured then the principal investigator will complete the Annual closeout/amendment/continuation form (Appendix VI) prior to the expiration of the approved IRB proposal.

Review of Proposed Changes in Current Programs

Please see SOP 15.99.05.W1.10AR Institutional Review Board for Human Subjects – Amendment of Research Procedure

The principal investigator shall immediately bring to the attention of the Chair of the IRB any changes which the principal investigator proposes to make in the program which may affect the status of the research or training as it relates to use of human subjects by completing the Annual closeout/amendment/continuation form. (Appendix VI).

The IRB will decide whether the extent or type of changes proposed warrant a formal review. If such a review is deemed necessary, the Chair shall schedule the review for the earliest feasible time. The principal investigator shall not incorporate the proposed changes until the IRB has given its written approval.

Continuing Review of Research Programs
Please also see SOP 15.99.05.W1.09AR Institutional Review Board for Human Subjects – Continuing Review of Research Procedure

It is the responsibility of the principal investigator to provide the IRB with a continuing review of protocols or projects involving human subjects that exceed twelve months. In these cases, the original protocol may be submitted, along with completing the Annual closeout/amendment/continuation form (Appendix VI), if no changes of human subject involvement have occurred. Any change of human subject involvement will require a new review and application.

Should a formal review be required because of changes in personnel, experimental procedures, or consent forms, the Chair of the IRB shall schedule the review at the earliest feasible time. The results of this review will determine if the program can be permitted to operate under the existing protocol.

Approval of continuing review will be transmitted to the sponsor (as required and in the specified format) by the IRB.

**Protocols of Projects of Non-University Sponsors**

Protocols of projects involving human subjects that are supported by non-University sponsors or protocols of projects submitted to non-University sponsors must be reviewed by the IRB. The IRB must be informed by the principal investigator of any special requirements of the sponsor regarding the involvement of human subjects.

Research projects by non-University sponsors and investigators using University students, faculty or staff as subjects must be reviewed by the IRB.

Cooperative research projects are those projects normally supported through grants, contracts, or similar arrangements with other institutions. In such instances, all institutions remain responsible for safeguarding the rights and welfare of human subjects. The IRB may enter into a joint review arrangement or accept the review of another qualified IRB.

A copy of the approval of the IRB of all institutions involved must be filed with the University's IRB.
Post Approval Monitoring System

Please see SOP 15.99.05.W1.11AR Institutional Review Board for Human Subjects – Post Approval Monitoring (PAM) Procedure.

Based on United States Department of Health and Human Services (HHS) regulations at 45 CFR 46.103(b)(4) and (5) require that institutions have written IRB procedures for which the IRB will follow for determining which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review.

Determining Which Projects Require Review More Often than Annually


This procedure describes the procedures relating to HHS regulation 45 CFR 46.103(b)(4) and (5) determining which projects require review more often than annually in the Institutional Review Board for Human Subjects (IRB).

Notice of IRB Action

Please see SOP 15.99.05.W1.05AR Potential Non-Compliance in the Course of Human Subjects Research.

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**

Please see SOP 15.99.05.W1.05AR Potential Non-Compliance in the Course of Human Subjects Research

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.

**Unanticipated Problems and Serious Adverse Events**

Please see SOP 15.99.05.W1.13AR Institutional Review Board for Human Subjects – Unanticipated Problems and Serious Adverse Events

The procedure requires investigators to promptly report all unanticipated problems involving risks to human subjects and others. This procedure describes the procedures relating to HHS regulation 45 CFR 46.103(b)(4) and (5) the procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, any Department or Agency head, and OHRP of:

(a) any unanticipated problems involving risks to subjects or others (hereinafter referred to as *unanticipated problems*);
(b) any serious or continuing noncompliance with 45 CFR Part 46 or the requirements or determinations of the IRB; and

(c) any suspension or termination of IRB approval.

PART III

Institutional Review Board

Composition of the Institutional Review Board and Selection of Its Members

1. Members of the IRB are appointed by the Vice President of Research and Compliance which recommends a nominee to the President of the University for approval. Members shall serve three-year terms, and there are no limitations on the number of terms a person may serve.

2. The IRB shall have at least seven voting members with varying backgrounds in order to promote a complete and adequate review of research activities involving humans to be conducted by or under the auspices of the University. The composition of the IRB shall include the following:
   (a) At least one faculty member from each of the five colleges.
   (b) At least one member who is not affiliated with the University and who is not part of the immediate family of a person who is affiliated with the University.
   (c) At least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are not in scientific areas.
   (d) The Vice President of Research and Compliance as an ex-officio, non-voting member.

3. Members will be chosen so that the IRB will be sufficiently qualified through the experience and expertise of its members and the diversity of its members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes, in order to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standard of professional conduct and practice. The IRB shall, therefore, include persons knowledgeable in these areas.
4. The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond, or in addition to, that available on the IRB. These individuals may not vote with the IRB.

5. No IRB member may participate in the IRB’s initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

6. IRB members are responsible for being informed on all IRB policies, procedures, and applicable laws and regulations. The members are expected to review all of the cases thoroughly and to attend and vote at the meetings of the IRB.

**Operation of the Institutional Review Board**

1. The IRB will meet, upon call by the Chair, to review proposed and continuing activities involving human subjects and to carry out its various responsibilities. The quorum required shall be no less than a simple majority of the voting members of the IRB. In the event of a tie, the chair shall vote to break the tie.

2. For review of research that is governed by U.S. Department of Health and Human Services regulations, the IRB quorum must include at least one member whose primary concerns are in nonscientific areas.

3. No member shall be involved in either the initial or continuing review of activity in which he/she has a conflicting interest as determined by the IRB, except to provide information requested by the IRB.

4. The IRB will adopt a variety of mechanisms to assure depth and breadth of review, including provisions for inviting individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. Also, the IRB may invite principal investigators to attend the IRB meeting for first-hand discussion with the IRB.

5. The IRB will determine that the criteria for approval are met and will recommend the frequency of continuing review and the nature and extent of any monitoring of the research or consent process to be required.

6. The Chair of the IRB will provide written notice to principal investigators of the disposition of their proposals. If the proposal is approved, the letter will include the period for which the approval is valid, the requirements for reporting any emergent problems involving human subjects, the requirement for prior review in changes in
procedures, and any other special terms and conditions. If the IRB stipulates changes or if it disapproves the proposal, the written notification will state the basis for this decision. The IRB is responsible for the continuing review system and may undertake site visits, interviews, or other methods for monitoring the conduct of research and consent processes.

PART IV

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
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

Contact Office

WTAMU Academic Research Environmental Health and Safety
(806) 651-2270
APPENDIX I
ETHICAL STANDARDS

ETHICAL AND PROFESSIONAL STANDARDS FOR USE OF HUMAN SUBJECTS IN RESEARCH

The responsible use of human subjects in research can be extremely important to the development of new knowledge in many areas. Responsible investigation involving human beings as subjects, however, demands that careful attention be given to questions of ethics and human dignity. During the War Crimes Trials following World War II, the Nuremberg Code was drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners. This Code has been widely adopted by investigators conducting studies on human beings and has served as the prototype of many later codes intended to insure that research involving human subjects would be carried out in an ethical manner.

Since 1947, various codes for the proper and responsible conduct of research involving human subjects have been developed by professional associations to guide investigators working in the various disciplines involved. Experience has shown that while these codes have been helpful, they are frequently difficult to interpret or apply, particularly in non-medical research projects which involve human subjects. As part of its work, the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research developed broader ethical principles to provide a basis on which specific rules could be formulated, criticized, and interpreted. These principals are discussed in the Belmont Report.

It is the researcher's responsibility to be in compliance with the most recent legal and ethical standards for research.

SOURCES OF INFORMATION

A. The Nuremberg Code
APPENDIX II

ADDITIONAL PROTECTIONS PERTAINING TO RESEARCH INVOLVING SPECIAL CLASSES

PREGNANT WOMEN AND FETUSES

The IRB and investigators must be particularly aware of the laws and ethical considerations dealing with certain categories of subjects including pregnant women, fetuses, and children.

A. No activity may be undertaken unless:

1. Appropriate studies on animals and non-pregnant individuals have been completed;

2. Except where the purpose of the activity is to meet the health needs of the mother or the particular fetus, the risk to the fetus is minimal and, in all cases, is the least possible risk for achieving the objectives of the activity.

3. Individuals engaged in the activity will have no part in:

   (a) Any decisions as to the timing, method, and procedures used to terminate the pregnancy, and
(b) Determining the viability of the fetus at the termination of the pregnancy; and

4. No procedural changes which may cause greater than minimal risk to the fetus or the pregnant woman will be introduced into the procedure for terminating the pregnancy solely in the interest of the activity.

5. No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of the activity.

B. Policy

1. No pregnant woman may be involved as a subject in an activity covered by this subpart unless:
   (i) the purpose of the activity is to meet the health needs of the mother, and the fetus will be placed at risk only to the minimum extent necessary to meet such needs; or (ii) the risk to the fetus is minimal.

2. No nonviable fetus may be involved as a subject in an activity covered by this subpart unless:
   (i) vital functions of the fetus will not be artificially maintained; (ii) experimental activities which of themselves would terminate the heart-beat or respiration of the fetus will not be employed; and (iii) the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

   (a) In the event the fetus ex utero is found to be viable, it may be included as a subject in the activity only to the extent permitted by and in accordance with the requirements of other subparts of this part.
   (b) An activity permitted under the above paragraph may be conducted only if the mother and father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if: (i) the purpose of the activity is to meet the health needs of the mother; (ii) his identity or whereabouts cannot be reasonably ascertained; (iii) he is not reasonably available; or (iv) the pregnancy resulted from rape.

3. No fetus in utero may be involved as a subject in any activity covered by this subpart unless: (i) the purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs; or (ii) the risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of
important biomedical knowledge which cannot be obtained by other means.

An activity permitted under the above paragraph of this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's consent need not be secured if: (i) his identity or whereabouts cannot be reasonably ascertained; (ii) he is not reasonably available; or (iii) the pregnancy resulted from rape.

4. Unless it has been ascertained whether or not a fetus ex utero is viable, a fetus ex utero may not be involved as a subject in an activity covered by this subpart unless: (i) there will be no added risk to the fetus resulting from the activity, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means; or (ii) the purpose of the activity is to enhance the possibility of survival of the particular fetus to the point of viability.

C. Activities involving the dead fetus, macerated fetal material, or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with any applicable state or local laws regarding such activities.

PRISONERS

A majority of the IRB shall have no association with the prison. The IRB will appoint one voting member of the IRB, either a prisoner or a prisoner representative, when an issue of research on prisoners is before the IRB.

A. IRB’s responsibilities. The IRB shall approve such research only if it finds that:

1. Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.

2. The risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.

3. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be
selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project.

4. The information is presented in language which is understandable to the subject population.

5. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participating in the research will have no effect on his or her parole; and

6. Where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

B. Permitted Research Involving Prisoners. Biomedical or behavioral research may involve prisoners as subjects only if:

1. Study of the possible causes, effects, and processes of incarceration and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.

2. Study of prisons as institutional structures or of prisoners as incarcerated persons provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.

3. Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction and sexual assaults) provided that the study may proceed only after the IRB has consulted with appropriate experts or,

4. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health of well-being of the subject.

CHILDREN

A. Informed Consent of the Child:

1. The consent of the involved must be obtained in certain circumstances. Under these rules, children are defined as "persons who have not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted."
2. It will be up to the IRB to determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. However, if the IRB determines that (i) the capability of some or all of the children is so limited that they cannot reasonably be consulted or (ii) that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and (iii) such benefit is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. The preference is that children over the age of ten sign a written consent.

B. Informed Consent of the Parents:

For research projects that pose minimal or low risk of harm to children, the IRB may find it sufficient to get the permission of only one parent for a child to participate in a project. Where there is a chance of greater-than-minimal risk and no direct benefit to individual subjects--but the project could yield general knowledge about the subject's disorder or condition--the permission of both parents must be obtained unless only one parent has legal responsibility for the child or unless one parent is deceased, unknown, incompetent, or not reasonably available.

C. Wards of the State:

1. Children who are wards of the state or some other agency can be included in research that presents more than minimal risk and no direct benefits to the children only if the research is related to their status as wards or conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

2. The IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role of advocate or member of the IRB) with the research the investigator(s), or the guardian organization.

**Expedited Review**

1. Most social, economic, and education research projects are subject to expedited review the
studies using children involve the following:

(a) Research conducted in established or commonly accepted educational settings, involving normal educational practices;

(b) Research involving the observation of public behavior;

(c) Research involving the use of educational tests; and

(d) Research involving the collection or study of existing data, documents, records or specimens.

2. However, in research involving survey or interview procedures, the children being surveyed or interviewed by an investigator may not be capable of recognizing that their responses to questions on sensitive issues could be potentially damaging to themselves or others. Therefore, it is appropriate that the IRB at least review such research to determine whether the rights and welfare of children participating as subjects are adequately protected and when the requirements of permission or assent can be waived.

APPENDIX III

SUMMARY OF IR

West Texas A&M University

Purpose of the IR

The IRB exists to ensure that proper procedures are followed to protect the privacy and physical/emotional well-being of human participants in research/survey projects conducted on the campus of West Texas A&M University or conducted off-campus by WTAMU faculty, staff, and/or students.

Approval Must be Obtained

All research and/or surveys (except those exempted under Section A, No.6, p.4) must have the approval of the IRB. Approval of the IRB is required by the Texas A&M University System, as well as various national and international laws and agreements including the Nuremberg Code, the Declaration of Helsinki, the Belmont Principals, APA Ethical Guidelines, and the Code of Federal Regulations, Title 45, Sections 46.101-46.409.

Review Procedure

1. Prior to initiating your research, read become familiar with the requirements in the Policy and Procedures for the Protection of Human Subjects in Research Manual.

2. Submit 1 copy of the following to the chair of the IRB (If you are unaware of the name of the current IRB chair, contact the Killgore Research Center, (651-2270):
(a) A completed copy of the IRB cover sheet (see Appendix V of the IRB "Policy and Procedures" manual), including the signed statement that you have read the required ethical and legal codes.

(b) A proposed "informed consent form for use in your research (see Appendix IV, Part A of the IRB "Policy and Procedures manual for examples).

(c) A brief synopsis of your proposed research, including:
   
i. All procedures and research protocols used with human subjects.
   
   ii. A description of the assessment instruments you plan to use.
   
   iii. Your plans to protect the confidentiality and safety of the human participants and of the data collected during the research.

(d) A copy of each assessment instrument you intend to use.

(e) A copy of any treatment or intervention protocols used with human participants.

3. The Chair of the IRB will review your proposal and distribute copies to all IRB committee members who then determine whether the proposal should be accepted as written, accepted with changes, or rejected. A formal meeting of the IRB may or may not be required to reach consensus.

   (a) If "accepted with changes," the required changes must be submitted to the Chair of the IRB and approved prior to initiating your research.

   (b) If "rejected," the research must be terminated or undergo significant changes and be resubmitted.

3. Upon being notified of acceptance, you may proceed with your research. The investigators must keep all signed informed consent forms on file.
APPENDIX IV

IRB EXEMPTION FOR SURVEYS

Surveys that are conducted by students as a single course assignment under the supervision of the course instructor are exempt from IRB review under the following conditions: (a) Participation is voluntary, confidential, and without penalty or reward; (b) the survey does not involve vulnerable populations (e.g., children, mentally disabled, institutionalized elderly, disadvantaged persons, or prisoners; (c) the survey does not deal with sensitive aspects of the respondents behavior such as illegal conduct, drug use, or sexual behavior.

Surveys conducted by WTAMU and its colleges, divisions or departments for the purpose of program evaluation and institutional effectiveness are exempt from IRB review.

To help determine if your survey is exempt from IRB review, we suggest you answer the following questions:

If any of questions 1-3 are answered "YES," the survey must be submitted to the IRB for approval.

QUESTIONS:

1. Does the survey involve any of the following?
- Children under the age of eighteen.
- Mentally disabled persons.
- Institutionalized elderly.
- Economically or educationally disadvantaged persons.
- Persons with limited civil freedoms such as prisoners, residents or clients of institutions for the mentally ill and mentally retarded, and persons subject to military discipline.

2. Does the survey require disclosure of any of the following?

- Illegal conduct.
- Drug use.
- Sexual behavior/sexually transmitted diseases.

3. Could the subject's responses, if made public, place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability?

If any of questions 4-9 are answered NO, "the survey must be submitted to the IRB for approval.

QUESTIONS:

4. Do you assume responsibility for the survey?

5. Do you assume responsibility for the preparation and training of students or staff administering the survey?

6. Is participation voluntary?

7. Is the confidentiality of the participants preserved?

8. Is there a written statement accompanying the survey informing participants of the following?

- A statement of the nature, purpose, procedures, risks, and benefits of the survey.
- A statement offering the subject the opportunity to ask questions and to withdraw at any time from the research.
- A statement assuring the subjects their participation is voluntary and does not carry any rewards or penalties.
- A statement assuring the subjects their participation is confidential and their participation will not be used in determining grades, employment, promotions, etc, as warranted by the situation.
- A means by which the investigator(s) may be contacted (e.g. phone number, P.O. box number, address).

9. If the survey involves another agency or institution, has agency approval been obtained.
APPENDIX V
CONSENT

INFORMED CONSENT

A. The elements of informed consent are the following:

I. Basic Elements:

(a) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(b) A description of any reasonably foreseeable risks or discomforts to the subject;

(c) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(d) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(e) A statement describing the extent, any, to which confidentiality of records identifying the subject will be maintained;
(f) For research involving more than minimal risk, an explanation as to whether any compensation and whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(g) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event or a research-related injury to the subject; and

(h) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

2. Additional Elements:

When appropriate, one or more of the following elements of information shall also be provided to each subject.

(a) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently enforceable;

(b) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(c) Any additional costs to the subject that may result from participation in the research;

(d) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(e) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(f) The approximate number of subjects involved in the study.

B. Exceptions

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

1. The research is to be conducted by or subject to the approval of state or local officials and is designed to study, evaluate, or otherwise examine:

   (i) Federal, state, or local benefit or service programs which are not themselves research programs,

   (ii) procedures for obtaining benefits or services under these programs,

   (iii) possible changes in or alternatives to these programs or procedures, or
(iv) possible changes in methods or levels of payment for benefits or services under these programs; and

2. The research could not practicably be carried out without the waiver or alteration.

C. Other Exceptions

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects;

2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;

3. The research could not practicably be carried out without the waiver or alteration; and

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participating.

Legal Requirements

The informed consent requirements in these regulations are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

Appendix VI

West Texas A&M University
The Office of Research
WTAMU Box 60217 Canyon, Tx 79016
806.651.2270

IRB Closeout/Continuation/Amendment Form

- Submit completed signed materials to the Office of Research WT Box 60217 Canyon, TX 79016 or deliver to Killigore Research Center, Room 106, OR 2) scanned and signed PDFs to ar- ehs@wtamu.edu

Title: ___________________________ Date: ___________________________

IRB Proposal #: ___________________________
**SECTION 1: INVESTIGATOR INFORMATION**

<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
<th>Dept/College</th>
<th>Email Address</th>
<th>Mailing Address</th>
<th>Phone Numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI*</td>
<td>Jane Doe</td>
<td>Ed/COESS</td>
<td><a href="mailto:jdoe2@buffs.wtamu.edu">jdoe2@buffs.wtamu.edu</a></td>
<td>2901 4th Ave.</td>
<td>H 555.555.5555</td>
</tr>
<tr>
<td>CI*</td>
<td></td>
<td></td>
<td></td>
<td>Canyon, TX 79016</td>
<td>C 555.555.1111</td>
</tr>
<tr>
<td>CI*</td>
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<tr>
<td>FA*</td>
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</tr>
</tbody>
</table>

**Review Type** (check one) □ Exempt □ Expedited □ Full Review

**Sponsoring Organization/Funding Source** (if applicable)

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**SECTION 2: OVERVIEW**

1. Check all that apply:
   - [ ] Closeout
   - [ ] Continuing Review – with changes (Check all that apply below)
   - [ ] Continuing Review – no changes
   - [ ] Amendment (Check all that apply below)
   - [ ] Adding key personnel or research assistants
   - [ ] Location changes
   - [ ] Conflict of interest changes
   - [ ] Inclusion criteria changes
   - [ ] Exclusion criteria changes
   - [ ] Recruitment – Advertisement
   - [ ] Compensation
   - [ ] Title change → New title: _________________________
   - [ ] Reopening enrollment
   - [ ] Removing key personnel or research assistants
   - [ ] Adding funding source → Include copy of the grant
   - [ ] Removing a funding source
   - [ ] Increasing participants → Number to add: ____________
   - [ ] Decreasing participants → Number to remove: ____________
   - [ ] Study procedures
   - [ ] Informed consent form
   - [ ] Instruments: adding, removing, changing
   - [ ] Other – Specify: _________________________

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**SECTION 3: CURRENT STUDY STATUS**

[ ] Data collection never initiated, enrollment not started, closing study. (Skip to “Section 9: Investigator Statement of Compliance”)

45
Study closing early, data collection was abandoned and already obtained data has been destroyed.

☐ Closeout - Data collection complete, enrollment closed, all data de-identified. (Completion date: ___ ___)

(Skip to “Section 5: PARTICIPANT INFORMATION”)

☐ Continuing Review, study is or will be actively enrolling new subjects.
☐ Continuing Review, no new participants to be enrolled, data collection continues.
☐ Continuing Review, no new data collection, analysis only.

☐ Amendment – (Attach consent form and any other forms that reflect the updates with application.) All changes must receive IRB approval before implementation.

SECTION 4: PERSONNEL

1. If adding personnel (involved in recruitment and/or data collection) list the following information for each person.

<table>
<thead>
<tr>
<th>Name / Title</th>
<th>Email</th>
<th>Phone number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department</td>
<td>Mailing address</td>
<td></td>
</tr>
</tbody>
</table>

2. If removing key personnel or research assistants, list their names and titles (if applicable) below and explain the reason for their removal.

3. If no other modifications are being requested, skip to Section 6 and attach CITI certificates for each new team member.

SECTION 5: PARTICIPANT INFORMATION

Since the beginning of the research project, please indicate:

<table>
<thead>
<tr>
<th>Total number of subjects who CONSENTED to participate</th>
</tr>
</thead>
</table>

<table>
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<tr>
<th>Total number of subjects COMPLETED the study</th>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Total number of subjects who WITHDREW during (or did not complete) the study, if known.*</th>
</tr>
</thead>
</table>

*If any subjects withdrew from the study, provide a brief explanation of the reason(s) for withdrawal, if known, below.

**If any unanticipated problems, including adverse events or subject complaints, occurred since the last IRB review, provide a detailed explanation, including what actions were taken. Please complete section 7 & 8.
SECTION 6: SPECIFIC AMENDMENT REQUESTS

1. Briefly describe the anticipated modification(s) and reasons for the request. (Attach any revised instruments, recruitment materials, updated consent form, etc.)

2. If the modification(s) may affect the risk to participants, please explain and include what measures will be taken to minimize these additional risks.

3. If this modification(s) may affect the benefit to participants, explain how.

4. If this modification may affect current participants’ willingness to participate in the study (i.e., revised study procedures, change in compensation, etc.), explain below.

5. If currently enrolled participants will be informed about the modification changes, indicate how.

   - Participants will complete a new informed consent form. → Submit the new informed consent form for review.
   - Participants will complete an addendum informed consent form. → Submit the addendum informed consent form for review.

SECTION 7: SUMMARY OF EVENTS

1. If any deviation occurred from the last IRB approved protocol AND/OR if any deviation occurred from the originally anticipated risks and/or benefits of the study, provide a detailed explanation, including actions taken to reduce risk or discomfort to subjects and/or to communicate new knowledge to subjects.

2. If any unanticipated problems, including adverse events or subject complaints, occurred since the last IRB review, provide a detailed explanation, including what actions were taken. Indicate whether you reported the event to the IRB, and if not, why.
SECTION 8: CLOSEOUT

1. If any untoward events that may have occurred to any participants with an asterisk (**) to give full details of any untoward consequences that may have occurred during the study and how these are handled/resolved.

SECTION 9: INVESTIGATOR STATEMENT OF COMPLIANCE

By submitting this form, I certify all information provided is accurate and that procedures involved in this project are conducted according to federal regulations and West Texas A & M University policies governing human subject research. I understand that I cannot initiate any changes in my protocol before I have received approval and/or complied with all contingencies made in connection with that approval.

Signature of Principal Investigator  Date (mm/dd/yyyy)

Signature of Co-Investigator (if applicable)  Date

Signature of Faculty Advisor (if not the PI)  Date

Signature of Department Head  Date

Important information regarding retention of informed consent forms and research records:
The principal investigator is expected to maintain records of consent as well as the research records for at least three (3) years after the close of the study, unless the study falls under the Health Insurance Portability and Accountability Act (HIPAA). For studies that fall under HIPAA regulation, consent forms and research records must be kept for a minimum of ten (10) years. Further guidance on signed informed consent form retention and destruction may be located at http://www.wtamu.edu/administration/risk-management-records-management-retention.aspx

If the research study falls within the purview of the Food & Drug Administration (FDA), the principal investigator is responsible for retaining the signed documents and research records for the period specified in valid FDA regulations.

IRB APPROVAL  (For WTAMU Institutional Review Board Use Only.)

This Form has been reviewed and approved by the West Texas A & M University IRB.
Authorized IRB Signature ________________________________
Printed Name ________________________________
Approval Date ____________