SOP No. 15.99.05.W1.10AR Institutional Review Board for Human Subjects - Amendment of Research Procedure
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Supplements TAMUS Regulation 15.99.05

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 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. 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.

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**PART I**

**Amendment 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.

Review of Proposed Changes in Current Programs

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 A).

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.

Disposition and Distribution of Reviewed Materials

The procedure for disapproved protocols is as follows: if the amended 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
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
Human Subjects Protection Program
(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 Killgore 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>
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<tbody>
<tr>
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<td>FA*</td>
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<tr>
<td>e.g.</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. Canyon, TX 79016</td>
<td>555.555.5555 H 555.1111 C 555.555.1111</td>
</tr>
</tbody>
</table>

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

Sponsoring Organization/Funding Source (if applicable)
SECTION 2: OVERVIEW

1. Check all that apply:

- Closeout
- Continuing Review – with changes (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
- Continuing Review – no changes
- Amendment (Check all that apply below)
- 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: ____________________________

SECTION 3: CURRENT STUDY STATUS

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

_mm/dd/yyyy
(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.
   - Name / Title
   - Department
   - Email
   - Mailing address
   - Phone number

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:

- Total number of subjects who CONSENTED to participate
- Total number of subjects COMPLETED the study
- Total number of subjects who WITHDREW during (or did not complete) the study, if known.*

*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	hree (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 ________________