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.
1. PURPOSE

1.1. 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). 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.

2. SCOPE

2.1. This procedure applies to education and quality improvement activities initiated at the request of the Institutional Review Board (IRB), IRB Chair, or IRB Administrator, and as specified in this SOP.

3. DETERMINING STUDIES THAT REQUIRE REVIEW MORE OFTEN THAN ANNUALLY

3.1. Specific Time Frames

The IRB conducts review of research at intervals appropriate to the degree of risk, but at least once per year. Continuing Review is required as long as the research remains active for long-term follow-up of subjects. Continuing Review is also required when the remaining research activities are limited to data analysis. Please review SOP No. 15.99.05.W1.09AR WTAMU Institutional Review Board Human Subject Research – Continuing Review of Research Procedure. A continuation request must be submitted to the IRB prior to the expiration of the proposal. Complete the Closeout/Amendment/Continuation form (Appendix A).

Investigators are required to submit a final report to close out their studies rather than just allowing their studies to expire. A final closeout report is submitted by the Principal Investigator (PI) to the IRB at the end of the twelve month approval period. Complete the Closeout/Amendment/Continuation form (Appendix A).

The IRB may determine that certain studies must be reviewed more often than once a year based upon the initial review or continuing review (e.g. 3 months, 6 months, 9 months, or 12 months).
Additionally, the IRB may require review after a predetermined number of subjects have been enrolled into the protocol.

Studies that might be considered for review more frequently than once per year include, but are not limited to:

- The use of vulnerable populations, including those identified in 45 CFR 46.111(b) and 21 CFR 56.111(b) as well as cognitively impaired persons or others determined to be vulnerable by the IRB
- Significant risks or potential serious impairment to the subject
- Research by investigators who have required corrective action in previous studies

### 3.2 Random Time Frames

Protocols may be selected randomly for audit or may be targeted for audit at the discretion of the IRB Committee or the IRB chair in collaboration with the Institutional Official. Situations that may warrant a targeted audit include, but are not limited to:

- A study conducted by an investigator who previously failed to comply with federal regulations or IRB policies
- Complex projects involving unusual levels or types of risk to subjects
- Studies conducted at an off campus site including international research
- Projects where continuing review information suggests that possible material changes occurred without IRB approval
- Studies not otherwise monitored (e.g.; single center, investigator initiated, unfunded, etc.)
- Investigator or research staff financial conflict of interest
- Institutional financial conflict of interest

During the course of an IRB audit information is gathered from IRB records and the investigator’s IRB records documents (such as consent forms). Information may also be gathered from multiple additional sources including, but not limited to;

- Incident reports
- Research staff
- Research subjects
Related Statutes, Policies, or Requirements

45 C.F.R., Part 46.103

System Regulation 15.99.01 – Use of Human Participants in Research

Contact Office
Office of Research
Institutional Review Board for Human Subjects
(806) 651-2270
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 Killgore Research Center, Room 106, **OR** 2) **scanned and signed PDFs** to ar-ehs@wtamu.edu

<table>
<thead>
<tr>
<th>Title:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB Proposal #:</td>
<td></td>
</tr>
</tbody>
</table>

**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></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CI*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CI*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FA*</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<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>H 555.555.5555 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 – no changes

☐ Continuing Review – with changes (Check all that apply below)
☐ Amendment (Check all that apply below)

☐ Adding key personnel or research assistants
☐ Removing key personnel or research assistants

☐ Location changes
☐ Adding funding source ➔ Include copy of the grant

☐ Conflict of interest changes
☐ Removing a funding source

☐ Inclusion criteria changes
☐ Increasing participants ➔ Number to add: __________

☐ Exclusion criteria changes
☐ Decreasing participants ➔ Number to remove: __________

☐ Recruitment – Advertisement
☐ Study procedures

☐ Compensation
☐ Informed consent form

☐ Title change ➔ New title: ______________________
☐ Instruments: adding, removing, changing

☐ Reopening enrollment
☐ 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:

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

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>☐</td>
<td>Participants will complete a new informed consent form. ➔ Submit the new informed consent form for review.</td>
</tr>
<tr>
<td>☐</td>
<td>Participants will complete an addendum informed consent form. ➔ Submit the addendum informed consent form for review.</td>
</tr>
</tbody>
</table>

**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 ________________