Academic Research
Environmental Health and Safety
WEST TEXAS A&M UNIVERSITY

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 159, **OR 2) scanned and signed PDFs** to ar-ehs@wtamu.edu

Title: **Date:**

IRB Proposal #

SECTION 1: INVESTIGATOR INFORMATION

Researchers/Advisors		Dept/College	Email Address	Mailing Address	Phone Numbers
Role	Name				
PI*					
CI*					
CI*					
CI*					
e.g.	*Jane Doe*	*Ed/COESS*	*jdoe2@buffs.wtamu.edu*	*2901 4th Ave. Canyon, TX 79016*	*H 555.555.5555 C 555.555.1111*

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)

Continuing Review – no changes

Amendment (Check all that apply below)

Unique Identifier (Example: Adding personnel – Jane Doe)

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:

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:)

(Skip to "Section 5: PARTICIPANT INFORMATION")

Closeout – Data collection complete, enrollment closed, storing data long-term.

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 in the space provided below:

- 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 transferring this study to a new Principle Investigator, please complete the information below.

Reason for Transfer of Study:

I, , am requesting the above referenced study to be transferred to . This amendment reflects the change of a new PI and I understand I am still responsible for this study until approved.

Will research data be transferred to the new PI?

Yes

Describe how data will be transferred and stored to ensure confidentiality of sensitive data:

No

Please explain how the data will be protected, stored, de-identified, or destroyed:

PI Signature:

I, **,** have read, understand, and accept the role as PI on the above referenced study. I am willing to assume the responsibility of this study and understand this change will be effective on the date this amendment requesting the change is approved. Furthermore, I understand any changes I make in the future to this study will require submittal of an amendment in accordance with WTAMU IRB procedures prior to implementation of the change.

New PI Signature:

4. **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 below of any untoward consequences that may have occurred during the study and how these are handled/resolved.
2. Please describe how the data will be stored if no de-identification takes place and how biospecimens will be disposed of, if applicable, in the space below.
3. Below, please explain information given to subjects regarding what to expect after closure of your research protocol and any additional actions the participants should take, if any.

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 (mm/dd/yyyy) _____

Signature of Co-Investigator (if applicable) _____ Date (mm/dd/yyyy) _____

Signature of Co-Investigator (if applicable) _____ Date (mm/dd/yyyy) _____

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: Dr. Rex Pjesky

Approval Date: