University of Texas Permian Basin Institutional Review Board Protocol Modifications Request Form

Project Title:

Principle Investigator:

Study ID #:

Instructions: Please complete this form to request modifications to an approved research protocol. Provide a detailed description of the proposed changes and their rationale. Attach any necessary supporting documentation.

Section A: General Information

1. Nature of Modification

[ ] Change in Research Objectives

[ ] Change in Research Design or Methods

[ ] Change in Participant Recruitment

[ ] Change in Informed Consent Process

[ ] Change in Data Collection or Analysis

[ ] Change in Personnel

[ ] Other (Specify here). Click or tap here to enter text.

1. Description of Proposed Modification – For each of the above categories you selected to change, please describe the change(s) you are proposing. Click or tap here to enter text.
2. Rationale for Modification: Explain why this modification is necessary, including any new information, unforeseen issues, or ethical considerations.

Click or tap here to enter text.

1. Are any of these changes the result of something that occurred during human participant interaction or an unexpected event?

[ ]  Yes. Please explain: Click or tap here to enter text.

[ ]  No.

1. How will the proposed changes impact the risks or benefits to research participants?

Click or tap here to enter text.

Section B: Impact Assessment

1. Impact on Participant Safety and Welfare: Explain how the proposed modification(s) may impact safety and welfare, including risk or benefits.

Click or tap here to enter text.

1. Impact on Data Integrity: Describe how the modification may affect the quality and integrity of the research data.

Click or tap here to enter text.

Section C: Supporting Documentation

1. Attachments: List any supporting documents, such as revised consent forms, recruitment scripts and materials, data collection instruments, or updated protocols. Attach all new/updated documents.

Section D: Certification and Signatures:

I certify that the information provided in this request is accurate and complete to the best of my knowledge.

Principle Investigator Signature: Date:

Co-Investigator(s) Signature: Date:

Section E: Review and Approval:

Decision:

 [ ] Approved

 [ ] Approved with Modifications

 [ ] Deferred for Additional Information

 [x] Not Approved

IRB Reviewer’s Signature: Date:

IRB Chair’s Signature: Date: