Request for Continuing Review (Renewal)
Texas A&M University-Commerce Institutional Review Board (IRB)
Texas A&M University-Commerce IRB Website

Office Use Only	
For Expedited and Full Protocols ☐ Approved ☐ Disapproved	**For Exempt Protocols** ☐ Validated as continuing to meet the criteria for Exempt status ☐ Not validated as continuing to meet the criteria for Exempt status
Comments/Recommendations: Date: Signature:	

IRB Protocol #: _____ **Principal Investigator:** _____

Student Investigator (if applicable):

Protocol Title:

Date this form and supporting documents are due: _____

Review Type: ☐ Full ☐ Expedited ☐ Minimal

Date IRB Approval Expires: Department: _____

Principal Investigator TAMUC Email Address: _____

Student Investigator TAMUC Email Address (if applicable): _____

Honors Thesis? ☐ Yes ☐ No

Project Status:

1. The status of this project is:

   ☐ Unchanged-actively enrolling subjects

   ☐ Requesting changes-actively enrolling subjects (please complete an amendment form)

   ☐ Enrollment closed - subjects still receiving research-related interventions

   ☐ Enrollment closed - all subjects have completed all research-related interventions and research remains active only for long-term follow-up of subjects

   ☐ Enrollment closed - remaining research activities are limited to data analysis only

   ☐ Project never started, protocol unchanged - requesting continuing review

   ☐ Project never started - requesting protocol be closed

   ☐ Completed - requesting protocol be closed

2. Number of subjects enrolled since the last IRB review: _____
   Number of subjects enrolled since the start of the research study: _____

3. Number of subjects who withdrew from the study since the last IRB review. (Include withdrawal by investigator and subject self-withdrawal.): _____

   Reasons: _____

4. Number of complaints about this research since the last IRB review:

   Describe: _____

5. Number of adverse events and other unanticipated problems involving risks to subjects or others since the last IRB review. (Adverse events include unanticipated psychological discomfort, negative physical reactions, experience of side effects, reports to authorities, and loss of consent forms or data collection instruments. If you have questions about what constitutes an adverse event, please contact the Office of Sponsored Programs at 903-886-5766. All adverse events must be reported promptly to the IRB.): _____

   Describe: _____

   If there were adverse events or other unanticipated problems, does this suggest revisions are needed to the consent form or to the protocol?

   ☐ Yes ☐ No

   If yes, describe the revisions: _____

6. Have there been any changes in the protocol since the last IRB review that you have not reported to the IRB?

   ☐ Yes ☐ No

   If yes, describe all changes in an attachment and include appropriate paperwork (e.g., request for amendment approval form, revised protocol, or revised informed consent). Examples of changes include a change in the title of the project; alterations to the methodology; and a change to the research question.

7. Is there any information from your studies or from elsewhere that indicates a need to modify this study or that may change the risk/benefit ratio of this study?

   ☐ Yes ☐ No

   If yes, please explain in an attachment. Include any relevant information that may have an impact on the continued safety and appropriateness of this study and any amendments that may be required.

8. Have there been changes to your conflict of interest statement or situation?

   ☐ Yes ☐ No

9. Have there been any changes in the membership of the research team?

   ☐ Yes ☐ No

   If yes, describe and complete an amendment form: _____

10. Has this project received external funding that was not reported to the IRB?

    ☐ Yes ☐ No

    If yes, **include a copy of the grant** with the continuing review form.

Brief status report or interim findings:

Please **provide a clean copy of the current consent form**, if your study requires one. The IRB will affix the approval and expiration date stamp and return it to you.

Instructions for Submission of Renewal Request: You may submit this form electronically to ResearchCompliance@tamuc.edu
☐ I am the Principal Investigator (PI). I am submitting this form electronically and this submission constitutes my signature. **Signature of PI (or Advisor if applicable):** **Date:**