Please e-mail form to lmanning@etbu.edu

EAST TEXAS BAPTIST UNIVERSITY
INSTITUTIONAL REVIEW BOARD

CONTINUATION/RENEWAL FORM

SUBMIT THIS FORM TO LMANNING@ETBU.EDU A MINIMUM OF TWO WEEKS PRIOR TO THE EXPIRATION DATE TO ALLOW TIME FOR PROCESSING

_____
IRB Number

Title of Project:

_____
Expiration Date

Principal Investigator(s): *I acknowledge that this represents an accurate and complete description of the research.*

Name of PI (typed) | Signature of Primary PI | Date

Department

PI's Address (Street, City, State, Zip) | Phone | E-Mail

Required IRB Training Complete: ☐ Yes ☐ No

(Training must be completed before application can be reviewed)

Name of Co-PI (typed) | Signature of Co- PI | Date

Department

PI's Address (Street, City, State, Zip) | Phone | E-Mail

Required IRB Training Complete: ☐ Yes ☐ No

(Training must be completed before application can be reviewed)

If there are additional PIs, provide information on a separate page.

Advisor (complete if PI is a student): *I agree to continue to provide the proper surveillance of this project to ensure that the rights and welfare of the human subjects are properly protected.*

Advisor's Name (typed)	Signature of Advisor	Date
Department		
Advisor's Address	Phone	E-Mail

1. Do you propose any changes in principal investigators for the research during the next continuation period?

☐Yes ☐No

If yes, list changes, submit vitae and explain why the changes were made.

2. Research Activity Status

☐ New subject enrollment still in progress

☐ Enrollment closed, but subjects are still undergoing study procedures.

☐ Enrollment closed, subjects have completed study procedures, but are still in follow-up

☐ Subject involvement completed, need approval for data analysis of **identifiable** data only

3. Subject Status

Number of subjects approved in original application:

Number of additional subjects approved in previous modifications/continuations (if any):

Are more subjects than currently approved needed/desired? If so, how many?

Number of subjects actively enrolled in study:

Number of subjects that have completed the study:

4. Summarize the purpose of the research, as originally approved, to include description of the study population, sample procedures and methodology.

5. Thoroughly describe your research progress to date including the reasons for continuing the research. Sufficient information is required in the summary so that the IRB can determine whether the research continues to fulfill the criteria for approval.

6. (a) Has the research protocol been modified from that originally approved by the IRB?
☒ Yes ☐ No

(b) If yes, please summarize changes.

(c) Did you submit these changes to the IRB as a modification to the original protocol?
☐ Yes ☐ No

7. Describe **in detail** any <u>new</u> changes to the currently approved protocol that you plan to implement in the next year and explain why each change is being requested. Attach copies of any new or revised instruments for review.

8. Describe any changes in the risks or benefits to subjects that have been identified during the previous approval period or that may result from any proposed changes.

9. Are you continuing to recruit participants? ☐ Yes ☐ No

If yes, please submit clean copies of the documents (flyers, letters, emails, etc) to be used for recruitment during the next continuation period.

10. Are you currently using a written consent form? ■Yes ☐No

If yes, please submit a copy of the **current** informed consent document(s) (with the IRB approval).

Also submit for IRB approval a clean copy of the consent document(s) (with no IRB approval), with any necessary or desired changes.

If no, please explain how you are ensuring that subjects are giving voluntary consent to participate in the research.

11. Reportable Events

Have any adverse events or unanticipated problems involving risks to subjects or others occurred during this last reporting period? ☐Yes ☐No

If yes, were these events previously reported to the IRB? ☐Yes ☐No If No, download the form from the IRB website, complete it and email it to Dr. LaShondra Manning, IRB Chair at lmanning@etbu.edu with this continuation/renewal form.

12. Have any subjects withdrawn or been withdrawn from the research?

☐Yes ☐No

If yes, state how many have withdrawn and describe the circumstances

13. Have there been any complaints about the research during this last reporting period?

☐Yes ☐No

If yes, please report and summarize the complaints and your response/action.

For assistance, please contact Dr. LaShondra Manning, IRB Chair, at 903-923-2088 or manning@etbu.edu