UNIVERSITY OF NORTH ALABAMA
Continuing Review

FORM: IRB RENEWAL APPLICATION

NOTE: An application for continuing review must be filed annually as long as data remain identifiable to the principal investigator (links or codes exist that allow identification of participants), even if data collection is closed, and the development of manuscripts is the only research-related activity. (Closure may be requested if the data have been de-identified according to the protocol to maintain confidentiality or if the data have been destroyed.)

If you are requesting both a modification of the protocol and renewal, complete this form and FORM: Modification of an Approved Protocol. If you are requesting a modification but not renewal/continuing review, use FORM: Modification of Approved Protocol only.

Principal Investigator(s):_____Email_____

College/School _____Department _____

Title of Research Project: _____

IRB Project number: _____ OSP#:_____

Date of Last Approval: _____

Expiration Date of Last Approval: _____

This application is for:

_____**Continuing Review WITHOUT Modification (Complete this form only)**

_____ **Continuing Review AND Modification**
(Complete this form and FORM: Modification of Approved Protocol also)

NOTE: New conflict of interest issues may require study modification.)

SECTION I. This section requests certain numbers and information about study circumstances to date. The second section is for describing events that lead to past or proposed changes in your procedures.

Subject Recruitment and Retention

Sample size APPROVED BY IRB	
Number of subjects approached for participation over life of study (to date)	
Number of subjects who declined participation after initial presentation of study (before starting)	
Number subjects screened (if applicable)	
Total number of subjects enrolled	
Number of subjects who have completed study	
Number of subjects who withdrew after starting study	
Number of subjects withdrawn from study by investigator (If any, *please explain)*	
Is recruitment still in progress? (yes-no)	

What questions did prospects have after the study was been explained to them?

What were the primary reasons given for choosing not to participate?

What questions did subjects have about the study once it was underway?

Consenting and Reconsenting

Did you assess prospects' comprehension of the study explanation?

☐ NO ☐ YES *IF YES, please describe how you did so.*

Have any events occurred (previously approved or requested in this application) which necessitated a change in the consent process in order to facilitate participant comprehension or reduce misunderstandings about the study?

☐ NO ☐ Yes *(Describe)*

Were subjects reconsented during this study?

☐ NO *(Go to next section)* ☐ YES

IF YES, estimate the percentage of people who chose not to continue at the time of reconsenting: _____%.
What were the reasons given by non-reconsenting participants for choosing to discontinue their participation in the study?

International, Community-Based/Community Participatory Research

Has any service, useful information or skill, or other form of empowerment or appreciation to the population, country, or community been provided as part of this study?

☐ NA ☐ NO ☐ YES (*Describe)*

Findings

Ongoing study: Have there been any interim findings from this study? Include any relevant multi-center trial reports.

☐ NO ☐YES *If YES, please summ*arize.

Has there been any new literature or communication that affects study procedures, risks to participants, or their possible willingness to continue?

☐NO ☐YES *If YES, please describe.*

Have any reports of study problems been filed? ☐NO ☐ YES

If YES, how many? _____
Please attach and describe here. If these reports resulted in changes in research procedures, please describe in section below requesting information about interim modifications to the study.
Please attach Unanticipated Event Form or Adverse Event Form.

Have you submitted or published any manuscripts from this study?

☐ NO ☐YES *If YES, please list.*

Complaints

Have you received any complaints about this study? ☐NO ☐YES

If YES, please describe. Include description of resolution of complaint(s).

Conflicts of Interest

Have any new issues of COI arisen that were not previously reviewed by the IRB and that require modification of the procedures or informed consent process and documentation?

☐NO ☐YES

If YES, please complete a Request for Modification of Approved Protocol, describing the issue and its management.

Changes in Research Procedures

Have you made any changes in research procedures since the last scheduled

IRB review? (Was the proposal modified?) ☐ NO ☐YES

If YES, describe briefly and attach the IRB approval letter for those changes.

Continuing review only: What is your appraisal of the current risk-benefit ratio?

_____Minimal risk (Potential harm/discomfort not greater than those encountered in everyday life or during routine physical or psychological examinations)

_____Greater than minimal risk but has potential direct benefit

_____Greater than minimal risk and no direct benefit but with potential to yield generalizable knowledge about the subjects' disorder or condition**.**

_____If risk is greater than minimal, are the risks reasonable in relation to the potential benefits? Please explain.

RENEWAL ONLY: ATTACH COMPLETE COPY OF THE CURRENTLY APPROVED PROTOCOL AND CURRENT CONSENT FORM.

RENEWAL WITH MODIFICATION: ATTACH THE FOLLOWING ITEMS
-COMPLETE COPY OF CURRENTLY APPROVED PROTOCOL,
-FORM: MODIFICATION OF APPROVED PROTOCOL, AND

-CURRENT CONSENT FORM.

Signature

_____

Typed name of Principal Investigator

_____

Signature of Principal Investigator

Date Submitted: _____