**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): Click here to enter text. Email: Click here to enter text.

College/School: Click here to enter text. Department: Click here to enter text.

Title of Research Project: Click here to enter text.

IRB Project number: Click here to enter text. OSP#:Click here to enter text.

Date of Last Approval: Click here to enter a date.

Expiration Date of Last Approval: Click here to enter a date.

**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.)***

**Continuing Review Approval**

**IRB Chair:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date Signed:\_\_\_\_\_\_\_\_\_\_\_\_**

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| Number of subjects withdrawn from study by investigator (If any, *please explain)* | Click here to enter text.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

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

Click here to enter text.

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

Click here to enter text.

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

Click here to enter text.

**Consenting and Reconsenting**

Did you assess prospects’ comprehension of the study explanation?

□ [ ] NO [ ] Yes *IF YES, please describe how you did so.*

Click here to enter text.

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 If YES, d*escribe here.* Click here to enter text.

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: Click here to enter text.%.

What were the reasons given by non-reconsenting participants for choosing to discontinue their participation in the study?

 Click here to enter text.

I**nternational, 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 If YES, d*escribe here.* Click here to enter text.

**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 below.

 Click here to enter text.

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 below.*

Click here to enter text.

Have any reports of study problems been filed? [ ] NO [ ]  YES

If YES, how many? Click here to enter text.

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.

Click here to enter text.

*Please attach Unanticipated Event Form or Adverse Event Form.*

 Click here to enter text.

Have you submitted or published any manuscripts from this study?

[ ] NO [ ]  YES *If YES, please list.* Click here to enter text.

**Complaints**

Have you received any complaints about this study? [ ] NO [ ]  YES

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

Click here to enter text.

**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.

Click here to enter text.

**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.*

 Click here to enter text.

**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. Click here to enter text.

**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**

Click here to enter text.

Typed name of Principal Investigator

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Principal Investigator

Date Submitted: Click here to enter a date.