**UNIVERSITY OF NORTH ALABAMA**

**HUMAN RESEARCH PROTECTION PROGRAM**

**FORM: MODIFICATION OF AN APPROVED PROTOCOL**

**Investigator:** Click here to enter text.

**Study Title:** Click here to enter text.

**IRB #** Click here to enter text. **Approval Date** Click here to enter a date.

**IRB Chair Approval: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**1. What change(s) do you wish to make? Check all that apply.**

Add or delete instruments

Change (substitute) instruments

Modify a selected instrument(s)— (add, delete or change items)

Add or delete variable(s)

Add or delete a category of participant (e.g., eliminate diabetics, add Hispanics, add students from other courses or student research pools). Please identify courses or subject pools.

Click here to enter text.

Change inclusion or exclusion criteria

Change study title (with or without other changes)

Add a vulnerable population

Change sample size

Add or change recruitment sites

Change recruitment strategies, e.g., recruitment media

Change content of recruitment materials

Change compensation plan

Change incentive plan

Change wording of consent document

Change method of obtaining or documenting consent

Change in investigator

Change in project staff ONLY (GRA, student or other assistants)

Obtain protected health information

Change strategies for protecting confidentiality or privacy

Change plan for data storage or dissemination)

Address new Conflict of Interest issue

Research has gained funding

Research has lost funding

**OTHER:** Click here to enter text.

**2. What is the stimulus for this/these change(s)?**

Unanticipated or adverse events have arisen

Prospects’ questions suggest ways to improve study explanation and consent form

Participants’ responses suggest that data collection instruments or procedures should be changed.

Recruitment is going very slowly *(Please provide numerical details about your recruitment, enrollment, retention, or completion in #3 below.)*

New information has arisen that suggests an additional population or category of participant should be included or deleted.

New information has arisen that prospective or current participants should know.

Reduce participant burden

Changes in funding require adjustments in study

Requirement of sponsor

COI issue requires change in procedure or disclosure to participants

**OTHER:** Click here to enter text.

**3. Please explain rationale or circumstances in detail.**

Click here to enter text.

**4. Describe what exactly will be added to or deleted from your currently approved protocol and what change(s) will be made to your protocol.**

Click here to enter text.

**5. What is the effect of the requested change(s) on participant burden?**

Click here to enter text.

None

Increases ---Please explain

Decreases--- Please explain

**6. Will the proposed change(s) affect the risk-benefit ratio for participants?**

No  Yes

**If YES, What is your specific appraisal of the new risk-benefit ratio?**

Click here to enter text.

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.

**\*For modifications involving only change in student personnel (other than as PI), attach IRB training certificates. You need not submit a revised protocol or a copy of the previously approved protocol.**

**Except for changes in student personnel, please supply (1) a new clean copy of the protocol with all changes incorporated and identified by boldface, underlining, or italics and (2) a copy of the currently approved protocol.**

***If you are changing any written instruments used in interactions with subjects (consent documents, recruiting scripts, data collection instruments), attach copies of revised document(s).***

***If you are adding or changing a vulnerable population, please complete and submit a new IRB Application Form and Research Protocol Form.***

***If your research involves specific on- or off-campus sites, such as Kilby Laboratory School, Continuing Education, UNA Health Clinic, or public or private schools, these sites must approve the changes before they can be implemented. Please supply approval letters from officials at those sites with your application for modification or after its approval by IRB but prior to implementation of changes.***