UNIVERSITY OF NORTH ALABAMA
HUMAN RESEARCH PROTECTION PROGRAM

FORM: MODIFICATION OF AN APPROVED PROTOCOL

Investigator: _____

Study Title: _____
_____

IRB #_____**Approval Date** _____

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.
_____
_____ 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 <u>project staff ONLY</u> (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:**

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:**

3. Please explain rationale or circumstances in detail.

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.

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

_____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 <u>new</u> 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.

***For modifications involving <u>only change in student personnel (other than as PI),</u> attach IRB training certificates. You <u>need not</u> 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.