FORM: MODIFICATION OF AN APPROVED PROTOCOL

Investigator: ______________________________________

Study Title: ________________________________________________

IRB #________________ Approval Date ____________ OSP # ____________

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 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:
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 new 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 generalizeable 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 only change in student personnel (other than as PI), submit only the application face page indicating a revision, this form with the option for “change of project staff only” checked, the revised IRB Application Study Personnel List (Application Page 2), and IRB training certificates for new staff as needed. 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 adding or changing a vulnerable population, please complete and attach the supplementary form appropriate to that population.

If your research involves specific on- or off-campus sites such as the Recreation Center, the Child Development Center, rural clinics, 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.