**IRB Study Modification Form**



IRB # Enter assigned IRB number

The submission of a modification form is required whenever any changes are made to an approved project or a project that has been determined to be exempt. This includes, but is not limited to the following changes:

* title change
* extension of end date
* research personnel
* recruitment methods
* location
* study population
* data collection materials
* informed consent documents
* advertisements
* confidentiality measures
* inclusion/exclusion criteria
* reports from a data safety and monitoring board
* addition of a test instrument

**Note: All changes must be submitted and approved by the IRB prior to their implementation unless the change is necessary to protect the safety of participants.**

1. Study Title:

2. Principal Investigator:

Department:

Phone: email:

3. Materials revised/amended/added

Protocol – if checked, attach copy of the revised IRB application with changes highlighted. (Protocol must have new version date on it.)

Consent Forms(s) – if checked, one copy the revised Consent form with changes highlighted. (All consent documents must have the IRB number, IRB expiration date and version date on them).

Other (Identify other approved or added IRB documents which you are modifying or adding):

(all documents must indicate revisions, additions, changes, and include new version date)

4. Summary of changes - Description and reason for each modification:

5. Will the revision/amendment/addition change the scope or research objectives of the project?

No Yes

If yes, please describe how the changes affect the scope or objectives:

6. Please list documents affected by the modification (all documents must be submitted for approval):