

## Project Modification or Amendment

Federal regulations require IRB approval before implementing proposed changes. Complete this form and attach the changed research documents. "Change" means any change, in content or form, to the protocol, consent form, or any supportive materials (such as the Investigator's Brochure, questionnaires, surveys, advertisements, etc.). This also includes addition of investigators.

Name of Principal Investigator:

Project Title:

Original IRB Approval #:

CURRENT STATUS OF PROJECT (check only one):

Currently in Progress (# participants entered: \_\_\_\_\_ )

Study has not yet begun (no participants entered)

Closed to participant enrollment (remains active)

# participants on therapy/intervention:

# participants in longterm follow up only:

THIS SUBMISSION CHANGES THE STATUS OF THIS STUDY IN THE FOLLOWING MANNER (check all that apply):

Protocol Revision

Revised Consent Form \_\_\_\_\_

Protocol Amendment

Addendum (new) consent form

Study Closed to participant entry

Addition of or alteration to investigators (include training certificates)

Study Terminated

Cosmetic revisions that do not alter the project (such as typos)

Enrollment temporarily suspended by sponsor

Other (specify):

1. Briefly describe, and explain the reason for, the modification or amendment. Include a copy of supportive documents with changes highlighted. Highlight modifications/additions to the consent form, protocol, research questionnaire, etc.
2. Does this revision/amendment revise or add a storage of samples component?    Yes    No
3. Does the change affect subject participation (e.g. procedures, risks, costs, etc.)?    Yes    No
4. Does the change affect the consent document?    Yes    No    If yes, briefly explain the changes:

Include the revised consent form with the changes highlighted. Will any participants need to be reconsented as a result of the changes?    Yes    No    If yes, when will participants be reconsented?

Revision/Amendment approved by IRB Committee:    Yes    No

Signature

Date