Samford University
Institutional Review Board

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.).

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
- ☐ Protocol Amendment
- ☐ Study Closed to participant entry
- ☐ Study Terminated
- ☐ Revised Consent Form
- ☐ Addendum (new) consent form
- ☐ 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 of IRB Chair Date