Protocol Modification

Brigham Young University–Hawaii

(Updated April 2014)

Please submit this form and any attachments as a *single* Word file to **boyd.timothy@byuh.edu** for pre-review by the IRB staff.

Protocol No. _____

Project Title: _____

Name(s) of Investigator(s): _____

E-mail Address: _____ Phone: _____

Additional Contact(s)

If additional contact information has changed since last IRB review, list all current contact(s) below. If no new information, go to Proposed Change(s).

Name: Affiliation:
Email:

Name: Affiliation:
Email:

Name: Affiliation:
Email:

Proposed Change(s)

Indicate each change for which you are seeking IRB review and approval (check all that apply):

☐ Change in study personnel (including change in PI)

☐ Change in the number of participants

☐ All other research changes

Revised protocol descriptions should state the specifics of the changes and should include: the rationale for the changes, a detailed description of the revised procedures, and an explanation for how the changes will affect the risk to the subjects.

Description of changes:

Revised Document(s)

This request requires the revision(s), addition(s), and/or deletion(s) to the following (check all that apply):

- ☐ Research Protocol
- ☐ Consent Form(s), Assent Form(s), Permission Form(s), and Verbal Script(s) including translated documents
- ☐ HIPAA Research Authorization Form(s)
- ☐ Recruitment Materials (e.g. ads, flyers, telephone or other oral script, radio/TV scripts, internet solicitations
- ☐ Script(s) or Information Sheet(s), including debriefing materials
- ☐ Instruments (e.g., questionnaires or surveys completed by participants)
- ☐ Other, Specify:

Attach all revised documents. Revised versions of documents previously approved by the IRB should be labeled as such (for example, revised on March 20, 2014).

Principal Investigator's (or Advisor's) Assurance

I agree to follow all applicable federal regulations, guidance, state and local laws, and university policies related to the protection of human subjects in research, as well as professional practice standards and generally accepted good research practices for investigators.

I verify that the information provided in this Protocol Modification form is accurate and complete. I will initiate change(s) to this research only after having received notification of final IRB approval (unless necessary to eliminate apparent immediate hazards to participants).

_____ Date: _____
Signature of Principal Investigator

_____ Date: _____
Signature of Faculty Advisor (if applicable)

FOR IRB USE ONLY:

Approved _____ Date: _____
IRB Member or Human Subjects Program Director