THE UNIVERSITY OF RHODE ISLAND

URI Office of Research Integrity

Initial Review of Human Subjects Research

IRB

Amendment Form / Changes to Research

Protocol Number:

Project Short Title:

1. Principal Investigator

Principal Investigator:

If any contact information has changed since last IRB review - provide below:

PI Name

University Academic Title | Phone Number

College/Department | Email

2. Additional Personnel

If additional contact information has changed since last IRB review, list all current contact(s) below. If no new information, go to Section #3.

Name | Phone Number

College/Department | Email

Name | Phone Number

College/Department | Email

Name | Phone Number

College/Department | Email

All URI personnel listed on this protocol will have access to information about IRB actions and the completion status of each individual's administrative and training requirements (CITI, COI disclosure). Note: Personal financial information provided in COI disclosures is not included.

3. Proposed Change(s)

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

- ☐ Change in study personnel (including change in PI) --> Complete **Appendix R - "Additional Co-PI's/Key Personnel"**
- ☐ Change in the number of participants --> Complete **Appendix T - "Change in the Number of Participants"**
- ☐ All other research changes

4. Description of Change(s)

Briefly describe the changes you are requesting:

5. Revised Documents

a. 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

  Upload into the IRBNet submission package:
  -- The most recently used consent document where all new revisions have been highlighted.
  -- A new, clean copy of the revised consent document with the bottom right corner BLANK
- ☐ 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:

For all items checked, provide 3 copies of the currently approved materials (marked as "current"), and the revised materials, one copy with change(s) underlined (or "tracked") and one copy with change(s) incorporated (clean). All materials should be submitted single sided.

6. Principal Investigator'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, including, but not limited to, the responsibilities described in the URI IRB policy.

I verify that the information provided in this Continuing Review of Human Subjects Research application is accurate and complete.

Principal Investigator (print) _____ Date _____