



Brandeis University

Committee for Protection of Human Subjects

Protocol Modification Request

All modifications to currently approved research are required to have BCPHS review and approval prior to implementation. A modification is defined by the BCPHS as a change that does not alter the overall character of the original project. Changes that do not adversely alter the overall risk-benefit profile of the study may receive an expedited review. The convened committee reviews proposed changes that may affect the willingness of enrolled subjects to continue participation and/or increase the risk to research subjects.

Instruction for Application: To submit the proposed revisions to your protocol for review by the BCPHS, please complete this form and attach any necessary supporting documents. If you have questions, e-mail irb@brandeis.edu. Submit one signed, hard-copy original delivered to the Office of Research Administration, Bernstein-Marcus Rm. 121, or mailed to Brandeis Committee for Protection of Human Subjects, MS #116, and one copy via e-mail to irb@brandeis.edu. Allow approximately three weeks for completion of the review process.

Research/Thesis Title: _____

BCPHS Protocol #: _____ **Principal Investigator:** _____

Academic Title: _____ Department: _____ Work Phone: _____

Home Phone: _____ E-mail Address: _____

Mailing Address/Mail Code (Campus or Home): _____

Project Support: Not Funded _____ Funded (or Pending) _____ Source of Funding: _____

P.I. of Contract or Grant: _____ Contract/Grant No. (if available): _____

1. Description of Modification:

Attach a description of and rationale for the proposed modification. Include a summary of the possible effects on risks and benefits to the subject(s), and procedures to manage risks. Changes that affect the risks or benefits to subjects may require revisions to the consent form. If this change will affect presently enrolled subjects, an addendum to the consent may be needed to re-consent these subjects. If changing the person identified as the principal investigator, please include a letter from the principal investigator indicating the change in responsibility and a letter from the new investigator accepting responsibility for the research. Changes in investigators usually qualify for expedited review. Include the following as needed:

- a. Description of Modification
- b. Revised Consent Form(s) - 1 copy with changes highlighted, 1 master copy for CPHS stamp
- c. Revised Study Instrument(s)
- d. Revised Recruitment Materials

2. Personnel Changes:

- a. Identify new personnel affiliated with this project and provide a summary of their responsibilities, qualifications and relevant experience.
- b. Identify personnel no longer affiliated with this project. _____, _____

3. Identify new agencies involved with the research activities. If a new facility is involved, provide a letter indicating support for the research from that facility. The letter must be on the facility's letterhead and contain a statement that the agency will, "review, abide by and comply with the procedures approved by the Brandeis Committee on Protection of Human Subjects."

Signature of Investigator: _____ Date: _____

Faculty Sponsor's Signature: _____ Date: _____

BCPHS USE ONLY: EXPEDITED _____ **CONVENED COMMITTEE** _____ **Date:** _____

Modification Action: Approve _____ Conditional _____ Other _____ Reviewed by: _____