



## HSRB POLICY AND PROCEDURE STATEMENT

**Policy/Procedure:** Modifications to Approved HSRB Projects

**Policy/Procedure ID:** 01-12-001                      **Effective:** December 5, 2001

Federal regulations (45 CFR 46.103(b)(4)) require review of any proposed changes to an existing research project involving human participants. At a minimum, in all cases of modifications, approval should be requested **before** any change is made.

The Chair of the Board may designate certain modifications to be approved in an administrative manner by the Administrator of the Board. These modifications are as follows:

- Project Title Changes
- Personnel changes – other than the Principal Investigator
- Changes to the number of subjects recruited, if the change is less than 50% of the initially approved number
- Contact (PI and/or advisor) address and telephone number changes
- Changes to the project advisor (for student projects)

The investigator will contact the Office of Research Compliance (ORC) in writing to request the change. The ORC will update the project database and files accordingly and inform the investigator of the approval of the change.

In general, any other project modifications will require submission of a Request for Modification/Addendum. These modifications include but are not limited to:

- Addition or removal of questionnaire or interview questions
- Changes to recruiting methods
- Changes to the number of subjects recruited, if the change is greater than 50% of the initially approved number
- Changes to consent form (addition or removal of information), with the exception of changes related to modification of information listed above as being handled via administrative approval

Note: Changes to questionnaire/interview question or consent form wording may require Board approval depending upon the nature of the changes. In general, changes that enhance the clarity of the information presented should be addressable via administrative means.