



## HSRB POLICY AND PROCEDURE STATEMENT

**Policy/Procedure:** Review of Modification Requests- Expedited Review

**Policy/Procedure ID:** 02-12-008                      **Effective:** December 4, 2002

### A. Background

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.

### B. Procedure

Some changes, as outlined in policy 01-12-001, can be reviewed through an administrative process. However, if the change is of the nature that requires the submission of a Request for Modification/Addendum form, the request is handled as follows.

1. The Principal Investigator (P.I.) submits a completed Request for Modification/Addendum form to the Office of Research Compliance (ORC) noting the project description and proposed changes along with the modified or new documents relevant to the request.
2. The ORC checks the form for completeness, logs it into the database, and submits it to the review process.
3. Two HSRB members review the requested modifications and determine a review outcome:
  - a. Approved as submitted
  - b. Conditional approval - the researcher must make changes or provide clarifications before final approval can be given
  - c. Request requires full Board review – the reviewers have determined that the modification increases the level of risk to participants to more than minimal. \*
4. The ORC notifies the P.I. and the P.I.'s advisor (if applicable), in writing, of the review outcome.

\*Minimal risk, as defined by the federal regulations (45 CFR 46.102(i)), means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life.