



HSRB POLICY AND PROCEDURE STATEMENT

Policy/Procedure: Review of Modification Requests- Full Board Review

Policy/Procedure ID: 02-12-007 **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 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 forms (e.g., consent, recruitment materials) relevant to the request.
2. The ORC checks the forms for completeness and logs the modification request into the database. The ORC determines if the modification is minor. If so, the ORC submits the request into the expedited review process. If not, the ORC makes copies for distribution to all HSRB members.
3. The modification request is distributed to the HSRB members in the packet of meeting materials one week prior to the monthly meeting.
4. The Board reviews the modification request at the monthly meeting and determines 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. Deferred – the Board does not have sufficient information to make a decision. Additional information is required from the researcher before the request will be reviewed by the Board.
 - d. Denied – the requested change cannot be implemented. Substantial changes must be made before the request can be re-submitted for review by the Board.

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5. The ORC notifies the P.I. and the P.I.'s advisor (if applicable), in writing, of the review outcome.