

IRB PROCEDURE STATEMENT

Procedure: Review of Amendment Requests - Full Board Review

Procedure ID: 02-12-007

Effective: December 4, 2002

Revised: January 17, 2019

A. Background

Federal regulations (45 CFR 46.108(3)(iii)) require that an IRB shall establish and follow written procedures for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that investigators will conduct the research activity in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB, except when necessary to eliminate apparent immediate hazards to the subject. Approval must be granted **before** any change is made.

B. Procedure

If the change must be reviewed by the full Board the request is handled as follows.

1. The Principal Investigator (P.I.) submits an Amendment Request form to the Office of Research Compliance (ORC) noting the project description and proposed changes along with the modified or new documents (e.g., consent, recruitment materials) relevant to the request.
2. The ORC checks the forms for completeness. The ORC determines if the amendment is minor (i.e., no more than minimal risk to participants*). If so, the ORC submits the request into the expedited review process (procedure ID# 02-12-008). If not, the amendment will be submitted for review at the next full Board monthly meeting.
3. The amendment request is distributed to the IRB members one week prior to the monthly meeting.
4. The IRB reviews the modification request at the monthly meeting and determines a review outcome:
 - a. Approved as submitted
 - b. Modifications Required – the researcher must make changes or provide clarifications before final approval can be given
 - c. Deferred or Information Required – 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.

Review of Request for Modifications - Full Board

- d. Disapprove – the requested change cannot be implemented. Substantial changes must be made before the request can be re-submitted for review by the Board.
 5. The ORC notifies the P.I. and the P.I.'s advisor (if applicable) of the review outcome. The notification letter and applicable document(s) can be located in the “Board Documents” section of the relevant project in IRBNet.
- *Minimal risk, as defined by the federal regulations (45 CFR 46.102(j)), 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.