

IRB PROCEDURE STATEMENT

Procedure: Amendment (Changes) Requests for Exempt, Expedited, and Full Board Projects

Procedure ID: 2022-11

Effective: December 4, 2002

Revised: January 17, 2019; May 2022

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 (i.e., **Amendment Requests**) 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 or amendment to the research study is made.

B. Procedure

An **Amendment Request** is handled as follows:

1. The Principal Investigator (PI) submits an **Amendment Request** Form to IRB via [IRBNet](#) noting the project description and proposed changes along with the amended or new documents (e.g., consent, recruitment materials) relevant to the request.
2. The IRB checks the Amendment Request form for completeness. The IRB determines if the amendment is minor (i.e., no more than minimal risk to participants*). If so, the IRB submits the request into the Administrative Review process or the expedited review process. If not, the amendment will be submitted for review at the next Full Board monthly meeting. The Amendment Request is distributed to the IRB members one week prior to the Full Board monthly meeting.
3. The IRB reviewers or Full Board reviews the modification(s) required determines a review outcome:
 - a. Approved as submitted.
 - b. Deferred or Information Required – the expedited reviewers or the Full Board does not have sufficient information to make a decision. Additional information is required from the researcher before the request will be reviewed again by the expedited reviewers or Full Board.
 - c. Modifications Required – the researcher must make changes or provide clarifications before final approval can be given.
 - d. Disapprove – the requested change cannot be implemented. Substantial changes

must be made before the request can be re-submitted for review by the expedited reviewers or Full Board.

4. The IRB notifies the PI, and the PI's advisor (if applicable), of the review outcome via [IRBNet](#). The notification letter and other applicable document(s) can be found in the "Board Documents" section under the "Reviews" tab 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 or during the performance of routine physical or psychological examinations or tests.