

IRB PROCEDURE STATEMENT

Policy/Procedure: Review of Amendment Requests – Administrative Review

Policy/Procedure ID: 2022-14

Effective: December 5, 2001

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 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.

The Institutional Review Board has designated certain amendments to be approved in an administrative manner by the Office of Research Compliance staff. 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)
- Changes to a project that has been classified as Exempt and *not* required to undergo continuing review.

Changes to questionnaire/interview question or consent form wording may require Full 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.

In general, any other project amendments will require Expedited Review or Full Board Review (see this procedure). These amendments 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 the information listed above as being handled via administrative approval

B. Procedure

1. The Principal Investigator (PI), or research advisor (if applicable), submits a completed Amendment Request Form to electronically into www.IRBNet.org, noting the project description and proposed changes along with the changed or new documents (e.g., minor edits – no substantive changes to the research protocol or documents) relevant to the request.
2. The IRB checks the Amendment Form for completeness and ensures that the submission can be reviewed through the administrative review process. If the submission cannot be reviewed administratively, procedures for reviewing Exempt and Full Board project amendments will be followed.
3. The submission is submitted for Administrative Review.
4. One IRB staff member reviews the requested modification(s) and determines a review outcome:
 - a. Approved as submitted
 - b. Information Required – the reviewer does not have sufficient information to make a decision. Additional information is required from the researcher before the request will be reviewed.
 - c. Modifications Required – the minor edits have not been made correctly or the Amendment Request is referred to Expedited or Full Board Review because the proposed amendments (changes) are substantive and/or other research project protocols or documents have been substantially changed [these vary greatly from the initially approved project protocol(s) and document(s)].
5. The IRB Administrator notifies the PI, and the PI's advisor (if applicable), of the review outcome via email. 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.