

IRB PROCEDURE STATEMENT

Policy/Procedure: Review of Amendment Requests – Administrative Review

Policy/Procedure ID: 01-12-001

Effective: December 5, 2001

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.

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 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 (Procedure ID# 02-12-008) or Full Board Review (Procedure ID# 02-12-007). 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 P.I., or research advisor (if applicable), submits a completed Amendment Request form to the Office of Research Compliance (ORC) electronically into www.IRBNet.org, noting the project description and proposed changes along with the modified or new documents (e.g. consent document, recruiting materials) relevant to the request.
2. The ORC checks the form for completeness and ensures that the submission can be reviewed through the administrative review process. If the submission cannot be reviewed administratively, procedures 02-12-007 or 02-12-008 will be followed.
3. The submission is submitted for administrative review.
4. One ORC 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.
5. The ORC notifies the P.I., and the research advisor (if applicable), of the review outcome via email. The official notification letter, and stamped consent document(s) (if applicable), can be located in the “Board Documents” section of the relevant project in IRBNet.