Revisions to Approved Research

Purpose

The purpose is to outline the policy and procedure for revisions to approved human research.

Definition

Revisions to research are changes requested by the Principal Investigator (PI) or funding sponsor to a previously approved project.

Modifications/Amendments are changes or additional information requested by the Institutional Review Board (IRB) or Exempt Review Committee (ERC) to any part of a research application or supplementary materials after review has been conducted and before approval may be granted.

Policy

Revisions to approved research, however minor, must be submitted by a Principal Investigator (PI) to the IRB or ERC for review. Requested revisions may not be implemented until the IRB or ERC issues final approval for the proposed changes.

Revisions may include, but are not limited to, the following, additions, removals, etc.:

- Co-investigators, research assistants or advisor
- Instruments
- Participating agency
- Participants
- Location of research, data access or recruitment
- Recruitment methods
- Recruitment documents (e.g., email message, flyer, brochure, etc.)
- Incentives
- Corrections or clarifications (e.g., typographic errors)

Approval of revisions does not extend a project's expiration date. Revisions will be reviewed under the same type of review as initial review, unless the original was full and the change is considered minor, in which case it might qualify for expedited review (see Expedited Review policy).

Procedures

1. If an investigator wishes to make a change, however minor, to an approved project, s/he submits a form to the appropriate board via IRBNet, as follows:

    1. Request for Revisions to IRB Approved Research form to the Institutional Review Board (Full or Expedited research), OR
    2. Revisions to Approved Research form to the Exempt Review Committee (Exempt research)
2. The investigator includes any additional documentation, as needed (e.g., revised consent form, additional instrument, training evidence for new research assistants, etc.). If a previously submitted document is being revised, all revisions must be tracked with the word processing software's tracking feature.
3. The Director of Human Participants Protection and Research Compliance, or a designee, reviews the requested revision and decides whether it is minor or requires review by a convened meeting of the IRB.
4. Once reviewed, the IRB or ERC decides to approve, require modifications to, or disapprove the proposed revisions (Note: An IRB cannot disapprove research or revisions under an expedited review procedure). The IRB or ERC issues a decision letter via IRBNet, which will send an automated email notice to the PI.
5. If modifications are required, the PI submits them for review.
6. With final approval, the IRB or ERC uploads the final approval letter and any stamped documents that are part of the consent process (e.g., consent form, recruitment email, flyer, etc.), if applicable.

Related Policies

- Approval of Research
- Continuing Review
- Expedited Review of Research (Minor Change)

History

06/14/2013 - Updated
06/27/2013 - Updated
04/02/2014 - Updated to include more examples
05/23/2018 - Added reference to Expedited Review policy and updated procedures