

IRB PROCEDURE STATEMENT

Procedure: Review of Modifications Required to Projects

Procedure ID: 02-08-001

Effective: August 7, 2002

Revised: January 17, 2019

A. Background

Frequently the initial review of IRB projects, amendment requests, and annual renewals identifies modifications that the researcher must address in order to obtain final approval.

The Institutional Review Board has designated responses to certain modifications to be approved in an administrative manner by the Office of Research Compliance staff. These conditions are as follows:

- Inclusion of/change to contact information (investigator and IRB)
- Inclusion of/change to specifically identified information or text (e.g., change “I understand...” to “I have been informed that...” addition of project title to consent document)
- Corrections to typographical and spelling errors on consent documents
- Printing of consent documents on BGSU (or other appropriate) letterhead
- Verification of documentation of approval by external organizations such as school districts, other IRBs, business organizations

Responses to other required modifications for final approval require review by the Chair or designated member(s). These modifications include but are not limited to:

- Revision of consent documents to reflect appropriate reading level
- Clarification or justifications requested by reviewers
- Inclusion of/change to elements of consent for which assessment of appropriateness of wording or presentation to participants is required
- Responses requiring full Board review.

B. Procedure

1. The P.I., or the research advisor (if applicable), submits the revised materials electronically into www.IRBNet.org.
2. The Office of Research Compliance (ORC) reviews the submission for completeness. The ORC notes the revisions that can be approved administratively and those requiring IRB member review.
 - The staff will review any responses for which administrative approval is appropriate and note the outcome in IRBNet.

- If there are responses that require IRB member approval, the project will be assigned to the member(s) and await review. The IRB member(s) reviewing the responses will note the outcome of the review(s) in IRBNet.
 - Approved
 - Modifications Required – the researcher must make changes or provide clarifications before final approval can be given
 - Information required – the reviewers do not have sufficient information to make a decision. Additional information is required before the request can be reviewed
 - Request requires full Board review – the reviewers have determined that there is substantial concern with the concern and that the risk to participants may be more than minimal risk.* If any single reviewer requests that a project be referred to the full Board, that request is honored.
 - If a full Board project requires revisions to be reviewed by the full Board, the revisions will be assigned to all members for viewing at the next full Board meeting.
3. 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.
- Additional responses to concerns will be addressed again through this procedure.
 - If full Board review is requested, the revisions will be assigned to all members for viewing at the next full Board meeting.

*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.