Bowling Green State University

Institutional Review Board
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IRB PROCEDURE STATEMENT

Procedure: Review of Modifications Required for Projects (Exempt, Expedited, Full Board Reviews, and Amendment Requests)

Procedure ID: 2022-08

Effective: August 7, 2002
Revised: January 17, 2019; May 2022

A. Background

Frequently after review of IRB project submissions for **Initial Reviews of Exempt, Expedited, and Full Board Reviews**, **Amendment Requests**, and Continuing Reviews for Expedited and Full Board Reviews, there are **Modifications Required** (i.e., required modifications/changes to the research project documents that the IRB Reviewers have requested be made prior to final approval) that the researcher must address in order to obtain final approval. These required modifications are to adhere to the Federal guidelines for research with human subjects.

The Institutional Review Board (IRB) has designated that some responses to certain **Modifications Required** can be approved with an Administrative Review by the IRB Administrator. 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, etc.)
- 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
- Other minor editorial changes that are needed

Responses to **Modifications Required** prior to Final Approval require review by the IRB Administrator as well as review by the Chair or Vice-Chair of the IRB or designated IRB committee member(s) or Full Board depending on the type of project being modified. These modifications required 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 that have previously required Full Board review.

B. Procedure

1. The Principal Investigator (PI), or the research advisor (if applicable), submits the revised materials electronically into IRBNet.

2. The IRB Administrator reviews the submission for completeness. The IRB Administrator designates whether these modifications required, or revisions can be approved administratively versus those requiring IRB committee member(s)' review.

   - The IRB Administrator 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.**
     - **Information Required** – the reviewers do not have sufficient information to make a decision. Additional information is required before the request can be reviewed again and approved.
     - **Modifications Required** – the researcher must make changes or provide clarifications before final approval can be given.
     - **Project Requires Full Board Review** – the reviewers have determined that there is substantial 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 unless otherwise changed by vote of the Full Board.

3. The IRB Administrator notifies the PI, and the research advisor (if applicable), of the review outcome via email through IRBNet. The official notification letter, and stamped consent document(s) (if applicable), can be found in the "Board Documents" section under the "Reviews" tab of the relevant project in IRBNet.
   - Additional responses to concerns will be addressed again, if necessary, by repeating 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 or during the performance of routine physical or psychological examinations or tests".