Institutional Review Board
irb@bgsu.edu
(419) 372-7716

IRB PROCEDURE STATEMENT

Procedure: Continuing Review of Approved Expedited Projects

Procedure ID: 2002-07 **Effective:** November 6, 2002
Revised: January 17, 2019; May 2022

A. Background

The Federal Regulations under the revised Common Rule in 2018 state that an institution can implement any kind of additional review that it wants as a matter of institutional policy for research conducted at that institution, and that **Continuing Review** for **Expedited Projects** can be required as a matter of policy if the IRB determines that continuing review is warranted for that category of research.

While the regulations [45 CFR 46.109(f)(1)(i)] *no longer require* expedited projects to undergo continuing review, the BGSU IRB *will continue to require* **Expedited Projects to undergo Continuing Review** no less frequently than once every 12 months. The rationale for this policy is that Expedited Projects approved by the BGSU IRB invariably involve private and identifiable information which, in case of breach of confidentiality, could present a risk in some way to the subject (e.g., emotional harm, harm to one's reputation, social relationships, job security, or legal/financial status). The BGSU IRB has determined that the need to ensure the use of appropriate consent forms and consent procedures, and the careful safeguarding of data and confidentiality, warrants the procedure of requiring Continuing Review every year for Expedited Projects.

This **Continuing Review** process must be substantive in nature and include all considerations addressed in initial review activities. Each continuing review must be conducted in accordance with the federally provided guidance and interpretation of the regulations that are current as of the time of the continuing review. As a result, the IRB may require updates to documents such as consent forms and introductory letters that had been approved when the project was last reviewed.

It is important for the **Continuing Review** to be accomplished before the current approval for the project expires because Federal regulations do not provide for a "grace period" extending the conduct of research beyond the expiration date of IRB approval.

The timing of a project's first **Continuing Review** is based upon the date of the initial review of the project, not the date on which final approval was given. For example:

- Initial review date of project "A" is June 5, 2018 at which conditional approval is given.
- Conditions are addressed and final approval is granted on July 1, 2018.
- The first continuing review and approval must be conducted on or before June 4, 2019 in order to prevent a lapse in approval.

The timing of subsequent continuing reviews is based upon the date on which the preceding continuing review and approval is effective. For example:

- Project "B" received continuing review and approval effective August 21, 2018.
- The next continuing review and approval must be conducted on or before August 20, 2019 in order to prevent a lapse in approval.
- When **Continuing Review** occurs annually and the IRB performs continuing review within 30 days before the IRB approval period expires, the IRB may retain the anniversary date as the date by which the continuing review must occur.

B. Procedure

1. The IRB Administrator will send a continuing review notice to the Principal Investigator (PI) and the project advisor (if the PI is a student) 60, 45, 30, and 15 days before the approval expiration date of the project.

2. The PI or the advisor submits the completed **Continuing Review** form electronically into IRBNet noting the project status (continuing or completed) and additional required information (such as number of participants, data collection status and participant withdrawals).

3. Current consent documents must be submitted into IRBNet if the PI has either enrolled participants in the project within the past year or is currently in the 'enrolling subjects' phase of the project.

4. The IRB Administrator and an assigned IRB member review the **Continuing Review** form for completeness and compare the submitted consent documents with the approved versions maintained in the project file. Any project that was initially approved before January 21, 2019 will continue to fall under the regulations in effect before the implementation of the revised Common Rule (i.e., will not need to revise consent forms according to the new required format).

5. If the project is continuing and consent documents match the approved versions, the project is submitted for continuing review and a determination of one of the following is made:
   - **Approved** as submitted (Continuing Approval).
   - **Information Required** – the reviewers do not have sufficient information to make a decision. Additional information is required from the researcher before the request will be reviewed.
   - **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 with the **Continuing Review** request 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.

The IRB Administrator notifies the PI and the advisor (if applicable) of the review outcome.

- Reponses to concerns are addressed through the Modifications Required procedure – then, after modifications are made and approved, the project can be **Approved.**
- If the modifications for approval are not addressed by the project expiration date, the PI is sent an "**expiration**" notice indicating that all subject recruitment and data collection must be stopped.
- Once the project is granted **Continuing Approval**, the project file is updated, and the PI and the PI's advisor (if applicable) are notified of the continuing approval and its duration via a notification email. The official notification letter and stamped consent document(s) and other applicable document(s) can be found in the "Board Documents" section under the "Reviews" tab of the relevant project in IRBNet.

6. If the submitted consent document(s) does not match the approved version(s), the following may occur:
   - The PI is contacted to explain the discrepancies.

   - The IRB Administrator requests the PI to provide all signed consent forms. If there is a discrepancy between the consent form that was used and the approved form, the IRB Administrator immediately informs the PI and the research advisor (if applicable), of the need to cease subject recruitment for the project (if ongoing subject recruitment is planned) until the IRB can review the situation at the monthly IRB Full Board meeting via email.

   - The PI and the research advisor (if applicable) are asked to provide a written explanation of why the approved protocol was not followed and an assessment of the impact of the protocol violation.

   - The IRB reviews the information at the monthly IRB Full Board meeting and decides about continuation of the study. Each project is considered on a case-by-case basis, but the range of outcomes includes, but is not limited to, project renewal, continued cessation the project, or project termination. Other stipulations may be attached including having the researcher obtain consent from the subjects again (re-consent), additional researcher (and/or advisor) training, and closer monitoring of the project by the IRB.

Note: Only Expedited and Full Board Projects undergo Continuing Review. **Exempt Projects do not undergo Continuing Review.** However, if *substantial changes* (i.e., Amendments) initiated by the PI (i.e., changes are made to the procedures, consent documents, etc.) than any Amendment requests for Exempt, Expedited or Full Board projects must be submitted as separate amendments for review via a different IRBNet "package (not in the Continuing Review form).

***** 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".