Institutional Review Board
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IRB PROCEDURE STATEMENT

Procedure: Continuing Review of Approved Full Board Projects

Procedure ID: 2022-10

Effective: March 3, 2004
Revised: January 17, 2019; May 2022

A. Background

Federal regulations [45 CFR 46 109(e)] require any research involving human subjects or participants to be reviewed no less frequently than once every 12 months, if it has gone through Full Board review. Regulations require the **Continuing Review** process to 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 started.

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 is 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. At each monthly IRB meeting, a list of Full Board projects tentatively planned for Continuing Review at the next monthly meeting is distributed to the Board and a primary reviewer (PR) is designated (or volunteers) to explain each project.

2. The IRB Administrator sends a Continuing Review reminder to the researcher and research advisor (if the researcher is a student) 60, 45, 30, and 15 days before expiration. The Principal Investigator (PI) must make sure it is submitted by the deadline for the upcoming Full Board meeting. The meeting dates and deadlines can be found on the BGSU IRB web site.

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

4. Current consent documents (dated) must be submitted if the PI has either enrolled participants in the project within the past year. If the PI is currently in the 'enrolling subjects' phase of the project a current consent document (not dated) to be used for future enrollment of subjects should also be submitted for IRB review.

5. The IRB Administrator reviews the **Continuing Review Form** for completeness and compares the submitted consent document(s) with the approved version(s) 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., the PI will not need to revise consent forms according to the new required format).

6. If the project is continuing and the submitted consent document(s) match the approved versions:

    - The IRB notifies the relevant Primary Reviewer (PR) when sharing the monthly full Board documents.

    - The project is submitted for **Continuing Review**. Potential outcomes of the review are:
        - Approved as submitted.
        - Deferred or Information Required – the Board does not have sufficient information to make a decision. Additional information is required from the PI before the request will be reviewed again and a decision rendered.
        - Modifications Required – the PI must make changes or provide clarifications before final approval can be given.
        - Disapprove – the project cannot continue. Substantial changes must be made before the request can be re-submitted for review and a decision rendered.

- The IRB notifies the PI and the advisor (if applicable) of the review outcome.
  - Responses to concerns are addressed through the Modifications Required Procedure.
  - 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 advisor (if applicable) are notified of the continuing approval and its duration via a notification email.
  - The official notification letter, stamped consent documents, and other applicable document(s) can be found in the "Board Documents" section under the "Reviews" tab of the relevant project in IRBNet.

7. If the submitted consent document(s) does(do) not match the approved version(s), the following may occur:

   - The PI and the advisor (if applicable) are contacted to explain the discrepancies.

   - The IRB 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 staff immediately informs the PI advisor (if applicable), via email, of the need to cease subject recruitment for the project (if ongoing subject recruitment is planned) until the IRB can review the situation.

   - The PI and the 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 (administrators, Chair and/or Vice-Chair, and/or Full Board) reviews the information makes a determination about the 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, or project termination. Other stipulations may be attached including having the researcher obtain consent from the subjects again (reconsent), researcher training, and closer monitoring of the project by the IRB.

   - The IRB's determination is communicated to the PI and advisor (if applicable).

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).