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IRB PROCEDURE STATEMENT

Procedure: Continuing Review Procedure – Full Board Projects

Procedure ID: 01-03-002

Effective: March 3, 2004
Revised: January 17, 2019

A. Background

Federal regulations (45 CFR 46 109(e)) require any research involving human 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

Continuing Review – Full Board Projects

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) for each project.

2. The Office of Research Compliance (ORC) sends a continuing review form to the researcher and research advisor (if the researcher is a student) 60, 45, 30, and 15 days before expiration. The P.I. 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 P.I., or the advisor (if applicable), submits the completed continuing review form into www.IRBNet.org, 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 must be submitted if the P.I. has either enrolled participants in the project within the past year or is currently in the 'enrolling subjects' phase of the project.

5. The ORC 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., 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 ORC 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
     - Modifications Required – the P.I. must make changes or provide clarifications before final approval can be given
     - Deferred or Information Required – the Board does not have sufficient information to make a decision. Additional information is required from the P.I. before the request will be reviewed by the Board.
     - Disapprove – the project cannot continue. Substantial changes must be made before the request can be re-submitted for review by the Board.

   - The ORC notifies the P.I. and the advisor (if applicable) of the review outcome.
     - Responses to concerns are addressed through the modifications required procedure (ID 02-08-001).
     - If the modifications for approval are not addressed by the project expiration date, the P.I. 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 P.I. and the advisor (if applicable) are notified of the continuing approval and its duration via a notification email.
  - The official notification letter and stamped consent documents(s) can be located in the "board Documents" section of the relevant project in IRBNet.

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

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

   - The ORC staff requests the P.I. to provide all signed consent forms. If there is a discrepancy between the consent form that was used and the approved form, the ORC staff immediately informs the P.I. 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 at the monthly IRB meeting.

   - The P.I. 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 reviews the information at the monthly IRB meeting and makes a determination 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 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 P.I. and advisor (if applicable).

Note: Occasionally amendments to a project are requested at the same time as continuing review. Any modified procedures, consent documents, etc. must be submitted as separate requires (i.e., different IRBNet "packages").