

IRB PROCEDURE STATEMENT

Procedure: Continuing Review of Approved Projects - Expedited

Procedure ID: 02-11-006

Effective: November 6, 2002

Revised: January 17, 2019

A. Background

The new federal Regulations under the revised Common Rule 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 such 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 policy of requiring continuing review.

The 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 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.

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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 Office of Research Compliance (ORC) will send a continuing review form to the P.I. and the project advisor (if the P.I. is a student) 60, 45, 30, and 15 days before the approval expiration date of the project.
2. The P.I. or the advisor submits the completed continuing review form electronically 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).
3. Current consent documents must be submitted into IRBNet 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.
4. The ORC reviews the continuing review form for completeness and compares 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:
 - Approved as submitted
 - 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 from the researcher before the request will be reviewed
 - Request 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 ORC notifies the P.I. and the advisor (if applicable) of the review outcome.

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- 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 P.I.’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) can be located in the “Board Documents” section 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 P.I. is 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., 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 meeting via email.
 - The P.I., 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 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 (re-consent), researcher training, and closer monitoring of the project by the IRB.

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

*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.