



HSRB POLICY AND PROCEDURE STATEMENT

Policy/Procedure: Continuing Review of Approved Projects - Expedited

Policy/Procedure ID: 02-11-006 **Effective:** November 6, 2002

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. 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 HSRB 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 HSRB 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, 2002 at which conditional approval is given.
- Conditions are addressed and final approval is granted on July 1, 2002.
- The first continuing review and approval must be conducted on or before June 4, 2003 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, 2002.
- The next continuing review and approval must be conducted on or before August 20, 2003 in order to prevent a lapse in approval.

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) one month before the approval expiration date of the project.
2. The P.I. or the advisor submits the completed continuing review form to the ORC noting the project status (continuing or completed) and additional required

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information (such as number of participants, data collection status and participant withdrawals), along with the current consent documents.

3. The ORC reviews the continuing review form for completeness and compares the submitted consent documents with the approved versions maintained in the project file.
4. If the project is continuing and consent documents match the approved versions, the HSRB Administrator notes this and the project is submitted for continuing review.
 - A. Two HSRB members review the file and determine a review outcome:
 - 1) Approval is granted for additional time period
 - 2) Concerns must be addressed before continuing approval can be given
 - B. The ORC notifies the P.I. and the advisor (if applicable) of the review outcome.
 - 1) Responses to concerns are addressed through the conditionally approved project review procedure (ID 02-08-001).
 - 2) If the conditions for approval are not addressed by the project expiration date, the P.I. is sent a "no longer approved" notice reminding him/her of the approval conditions to be addressed and that subject recruitment must be temporarily stopped until continuing approval is granted.
 - C. Once the project is granted continuing approval, the database is updated and the P.I. and the P.I.'s advisor (if applicable) are notified, in writing, of the continuing approval and its duration.
5. If the project is continuing and the submitted consent documents do not match the previously approved versions, the P.I. is contacted to explain the discrepancies and, if written consent has been obtained from participants, is requested to provide copies of signed consent forms. If there is a discrepancy between the consent form that was used and the approved form, the HSRB Administrator will immediately inform the researcher, and the research advisor, if applicable, of the need to cease subject recruitment for the project until the Chair can review the situation and make a determination about continuation of the study. Each project will be considered on a case-by-case basis. 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 more intense monitoring of the project by the HSRB.

Note: Occasionally modifications to a project are requested at the same time as continuing review and approval. Any modified procedures, consent documents, etc. approved during the continuing review process supercede prior versions and will be considered the most current versions for purposes of future continuing reviews and any additional project monitoring that may occur.