



HSRB POLICY AND PROCEDURE STATEMENT

Policy/Procedure: Continuing Review of Approved Projects - Exempt

Policy/Procedure ID: 02-11-005 **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. 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 HSRB may require updates to documents such as consent forms and introductory letters that had been approved when the project started.

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

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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.
 - a. If the project status is completed, the database is updated and the project documents are filed accordingly.
 - b. If the project is continuing and consent documents match approved versions, the review is handled administratively and the project is granted continuing approval.
 - c. If the submitted consent document(s) does not match the previously approved version(s), the P.I. is contacted to explain the discrepancies. When the P.I.'s explanation of the discrepancies is received, it is forwarded to the Chair of the HSRB for a determination of the action to be taken. The range of outcomes of this determination includes, but is not limited to, project renewal, having the researcher obtain consent from the subjects again (reconsent) and researcher training.
4. 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.