



## HSRB POLICY AND PROCEDURE STATEMENT

**Policy/Procedure:** Continuing Review Procedure – Full Board Projects

**Policy/Procedure ID:** 01-03-002                      **Effective:** March 3, 2004

### 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.

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. At each monthly HSRB 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 volunteer) 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) at least a month before the regularly scheduled monthly HSRB meeting at which a request for the project to continue is to be reviewed.

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3. The researcher 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.
4. Upon receipt of the continuing review information regarding each project, the ORC notifies each PR of the status of his/her assigned/designated project. If a project is completed, the PR is notified that no review is necessary. If a project is continuing, the PR is notified and is expected to review the entire history of the project before the monthly meeting and to be prepared to present it to the Board at the meeting.
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.
6. If the project is continuing and the submitted consent document(s) match the approved version(s), the ORC notes this on the continuing review form and the project is scheduled for continuing review at the monthly HSRB meeting.
7. If the submitted consent document(s) does not match the approved version(s):
  - The HSRB Administrator immediately requests the researcher to provide all signed consent forms. If there is a discrepancy between the consent form that was used and the approved form, the HSRB Administrator immediately informs the researcher and the research advisor, if applicable, of the need to cease subject recruitment for the project (if ongoing subject recruitment is planned) until the HSRB can review the situation at the monthly HSRB meeting.
  - The researcher and the research advisor, if applicable, are informed of this decision via email. The researcher 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. This information is provided to the Board for review at the monthly HSRB meeting.
  - The HSRB reviews the information at the monthly HSRB 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 HSRB.