Office of Research Compliance
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IRB PROCEDURE STATEMENT

Procedure: Review of Amendment Requests- Expedited Review

Procedure ID: 02-12-008

Effective: December 4, 2002
Revised: December 23, 2016

A. Background

Federal regulations (45 CFR 46.103(b)(4)) require review of any proposed changes to an existing research project involving human participants. At a minimum, in all cases of amendments, IRB approval must be obtained **before** any change is made.

B. Procedure

If the change can be reviewed through expedited review the request is handled as follows.

1. The Principal Investigator (P.I.) submits a completed Amendment Request form to the Office of Research Compliance (ORC) noting the project description and proposed changes along with the modified or new documents (e.g. consent, recruiting materials) relevant to the request.

2. The ORC checks the form for completeness, and submits it to the review process.

3. Two IRB members review the requested modifications and determine a review outcome:

   a. Approved as submitted
   b. Modifications Required - the researcher must make changes or provide clarifications before final approval can be given
   c. 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.
   d. Request requires Full Board review – the reviewers have determined that the modification increases the level of risk to participants to more than minimal*.

4. The ORC notifies the P.I. and the P.I.'s advisor (if applicable), of the review outcome. The notification letter and applicable documents can be located in the "Board Documents" section of the relevant project in IRBNet.

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*Minimal risk, as defined by the federal regulations (45 CFR 46.102(i)), 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.