

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH	Human Research Protection Program Policies & Procedures	
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Title: Review and Monitoring of Research Projects	Date Effective 6/09/04	Supercedes P&P dated

Revisions Before Final Approval

JHSPH POLICIES AND PROCEDURES

A common outcome of exempt, expedited or full committee review is a request that the research proposal or study documents be revised. The Principal Investigator must respond satisfactorily to all requests for revision or clarification before the proposal can be formally approved by CHR. The goal of CHR is to work with investigators to ensure that human subjects are protected in such a way that their projects ultimately may be approved.

If a study is classified as exempt or is receiving an expedited review, the PI should respond directly to questions and requests from the reviewer and revise the application. When the reviewer is satisfied with the revised application or the PI's responses, he or she will approve the study and decide when the continuing review would be due. If the reviewer is not satisfied, the application, together with the reviewer's comments, will be reviewed by the full committee.

If the initial review of an application is by the full committee, the investigator will receive a letter summarizing the committee's questions and requested revisions. If the requested changes are minor, and the only requirement is that the investigator agrees to the requested changes, the Committee may delegate review and final approval of the changes to a Co-Chair or a single CHR reviewer under an expedited review procedure. If, however, the reviewer is not satisfied, the application, together with the reviewer's comments, will be reviewed by the full committee.

If the full committee requires revisions that are more than minor, the revised proposal must be reviewed by the full committee at a regularly convened meeting.

Guidance on submission of revisions

1. Provide a cover letter to CHR indicating the name and CHR number of the study. The letter should respond fully to each of the committee's requests or questions, numbering the responses individually and in the same sequence as in the committee's letter.

2. To speed review and provide clear records, submit two full copies of the revised research plan or other documents, such as consent forms or research instruments, that include all additions, deletions and revisions. One copy should be the old approved version in which all changes are marked so they may be readily identified. (This is best done using the MS Word "Track Changes" tool.) The second copy should be an unmarked revision in which all changes have been incorporated. (This is done by selecting "Accept Changes" in the MS Word program.) The clean copy will become the official copy on file with CHR.
3. Revised research plans, consent forms and other documents should include the CHR study number, revision dates and version numbers on each page as a header or footer.