

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH	Human Research Protection Program Policies & Procedures	
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Title: Changes and Amendments to Approved Research	Date Effective 01/03/06	Supercedes P&P dated 04/11/05

BACKGROUND

Federal regulations require that IRBs review and approve all proposed changes in, and amendments to, previously approved research before the changes are initiated, except when a change is necessary to eliminate immediate hazard to subjects. Changes and amendments to approved studies may alter the risk/benefit ratio for research subjects. Initiating changes without prior approval by CHR is a violation of federal regulations.

JHSPH POLICY AND PROCEDURES

All changes and amendments to previously approved studies must be reviewed and approved by CHR before they are initiated.

Changes That Do Not Alter the Risk/Benefit Ratio

Changes to approved studies that do not alter the risk/benefit ratio associated with a study are considered minimal risk changes. These changes do not need to be reviewed at a convened meeting of the full committee and may be reviewed on an expedited basis by one or more CHR reviewers and/or Co-Chairs of the Committees.

Examples of Minimal Risk Changes:

- Changes in recruitment methods, e.g. revised advertisements
- Study title changes
- Addition or removal of investigators
- Minor changes in the Investigator Brochure
- Changes to improve the clarity of statements in consent documents
- Minor change in dose or drug
- Corrections to typographical errors in consent documents

Changes or Amendments that May Alter the Risk/Benefit Ratio

Changes to previously approved studies that alter the risk/benefit ratio associated with a study are considered greater than minimal risk changes. Such changes must be reviewed at a convened meeting of the full committee.

Examples of Greater than Minimal Risk Changes:

- Changes in study design
- Adding/requesting a Certificate of Confidentiality
- Additional arm or population added to the study
- A change in the amount or type of specimen collected, e.g. blood
- New information regarding safety of a study drug or device
- Major change in dose or drug
- Change in sample size
- Change in study eligibility criteria
- Change in duration of subject participation period
- Major changes in the Investigator Brochure
- Additional radiation exposure
- Adding the audio-taping and video-taping of subjects

The above-mentioned examples are presented as general guidelines only. All proposed changes and amendments will be reviewed by CHR to determine whether they can be handled by expedited review or require full committee review. If a proposed change could affect the subjects' willingness to continue participating in the study, the investigators may be required to re-consent *all* subjects enrolled in the study, using either an addendum to the original consent document or a revised consent document.

Procedure for Submitting Proposed Changes or Amendments for CHR Review

1. Provide an Amendment Request Form that includes the following information: type of amendment, description of amendment and how it will affect subjects already enrolled to the CHR.
2. When submitting an amendment request to proceed with the next phase of a multi-phase study, the results to-date should be summarized, including the number of subjects enrolled in the previous phase(s), knowledge gained from the previous phase(s), any unanticipated problems encountered and how they were resolved, and DSMB or safety monitor reports. This information should be included in the cover memorandum for the amendment request.
3. To speed review and provide clear records, submit (1) an original and three copies of the previously approved study documents with all deletions, additions and changes marked so they may be readily identified (this is best done using the MS Word "Track Changes" tool), and (2) an original and three copies of the same revised study documents in which all proposed changes have been incorporated, but without "tracking". Tracking can be removed by selecting "accept changes" in the MS Word program. All study documents in which changes are being proposed should be provided, including the research plan, consent forms and any other research instruments. One of the clean copies will be kept as the official copy on file with CHR.
4. 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.