**FHS006hlp: Preparing an amendment - Pointers for researchers**

* All changes to research protocols, information/consent documents, advertisements, study instruments and the like must have HREC approval prior to implementation except where necessary to eliminate immediate hazards to enrolled participants.
* All amendments should include a **Synopsis** for the amendment.
* Use the current version of the Amendment Form (FHS006) on the HREC website. If the amendment involves only a change to study staff, use the Staff Study Amendment Form (FHS007).
* If the amendment involves a change in Principal Investigator (PI), include a CV, a revised ‘conflict of interest’ statement and PI’s Declaration (Sections 7 and 8.4 in the New Protocol Application Form) signed by the new PI.
* Ensure that the revised documentation requiring approval carries the correct version numbers and dates.
* Provide a general motivation for the amendment and a rationale for each change.
* Address the impact of the amendment on participants’ safety and on the overall risk: benefit ratio of the study.
* Submit one copy of each amended document which clearly identifies changes. This can be done either as ‘old text’ replaced with ‘new text’ or with old text deleted with a strikethrough line and the new text shown in bold, italics or underlined. Use of tracked changes is also acceptable.



Old Text:

New Text:

Reason for Change:

* Submit one clean copy of each amended document (e.g. protocol, consent/assent forms).
* Failure to submit both copies (one copy with changes and one clean copy) and to provide rationales for proposed changes will delay the approval process as incomplete submissions will be returned to the PI.
* The Chairperson or designee will determine whether an amendment requires full-committee review in which case the HREC will notify the PI orally or in writing and will request additional copies of the amendment for circulation among Committee members before the next HREC meeting. Amendments which include substantial changes (e.g. changes that result in an increased risk to participants and/ or significantly affect the study design) may require a full-committee review. Examples of minor and substantial (major) modifications are provided below:
* Researchers can notify the HREC, **via a letter** of minor modifications to retrospective medical record reviews or clinical audits. Examples could include the wording of the study, title or minor adjustments to the number of patients or duration of the study. It is not necessary to submit an amendment form (FHS006).

**Minor modifications**

* A change that would not materially affect the assessment of risks and benefits in the study.
* A change that does not substantially affect the study’s aims or design.
* An increase or decrease in sample size, supported by a statistical justification.
* Administrative changes such as contact details, addition or removal of key personnel and/ or study sites.
* Narrowing the range of inclusion criteria.
* Broadening the range of exclusion criteria.
* Alterations in oral forms of administration of a drug e.g. tablet to capsule or liquid, as long as the dose remains constant.
* Changing data collection points or amounts of data collected as long as it does not alter safety evaluations.
* An increase in safety monitoring resulting in more frequent visits or an increase in the length of hospitalisation.
* Changes in compensation with adequate justification.
* Editorial changes that clarify but do not alter the existing meaning of a document.
* Translations of materials already reviewed and approved by the HREC.

**Substantial (major) modifications**

* Broadening the range of inclusion criteria
* Narrowing the range of exclusion criteria.
* Alterations in the dosage or route of administration of a study drug.
* Extending significantly the duration of a study.
* Removal of laboratory tests, monitoring procedures or study visits directed at gathering safety information.
* Appearance of new, serious unexpected adverse events or significant risks.
* New study documents to be distributed to or seen by participants that include information or questions substantively different from materials already approved by the HREC.

**US Federally-funded Research — Eligibility for Expedited Review of Amendments**

The HREC may use an expedited procedure to review proposed amendments in previously approved research in the following circumstances (45 CFR 46.110(b)(2):

1. Modifications to protocols previously approved by a full committee if the changes meet the following criteria:
   1. Changes do not pose an increased risk to subjects; AND
   2. Changes constitute a minor change to previously approved research.
   3. All added procedures fall within categories 1-7 of research that may be reviewed using an expedited procedure (45 CFR 46.110(b)(1).
2. Modifications to protocols previously approved by an expedited procedure if the changes meet the following criteria:
   1. With the changes, the research continues to pose no more than minimal risk to subjects.
   2. The changes do not involve any procedures that do not meet expedited categories 1-7.

For further information on the HREC website see: Eligibility for Expedited Review of US Federally-funded Research — Pointers for Researchers

**Submit Amendment (FHS 006 Form) and supporting documentation in a single combined PDF via email to: hrec-enquiries@uct.ac.za**