Reporting During the Course of a NON CTIMP Study

For Cambridge Sponsored CTIMPS contact the Cambridge Clinical Trials Unit (CCTU) for advice.

This guidance is for NON CTIMP sponsored studies only

The study may undergo monitoring by the study sponsor to ensure adherence to the Research Governance Framework. In addition to annual reports to the funder and the R&D Office, the following reports are also required:

- For all studies that have received REC approval you need to submit an Annual progress report
  A progress report must be submitted to the main REC each year of the study's duration.
- For studies that require Notification of substantial amendments notify the REC and R&D office that gave NHS capacity and capability for your study for approval. See below for further guidance.
- For studies that need to provide Safety reports both the REC and sites involved will need to be informed.
- RECs and R&D Offices need to be informed when a study has finished. Researchers should complete an End of study and final report for the REC and copy this to the R&D Office.
- Templates can be found on the HRA website

Study Amendments:

Amendments are changes made to the research after a favorable ethical opinion has been given for a study. They can be 'substantial' or 'non-substantial'.
The legal responsibility to decide whether an amendment is substantial lies with the trial Sponsor.

In all other research, advice can be sought from the Sponsor as to whether or not a proposed amendment is substantial and requires ethical review.
Examples of substantial and non-substantial amendments can be found here.

- An amendment form in IRAS can be generated by opening the study, highlighting the REC application on the Navigate page and then selecting the Amendment tab.
- If the original application was submitted prior to the IRAS procedure a minimum dataset needs to be created in IRAS to obtain the amendment form.
- All substantial amendment forms require a signed sponsor declaration page before they can be reviewed by the Research Ethics Committee.
- The R&D office will review proposed amendments and sign the declaration page

The REC will issue an ethical opinion on the amendment within a maximum of 35 days from the date of receipt of a valid notice of amendment.

Substantial amendments can receive a favourable, provisional or unfavourable opinion from the REC.

The REC usually offers advice/reasons for amendments receiving unfavourable opinion. Advice can also be sought from the R&D Office.

Non-substantial amendments and projects that do not have NHS REC approval are notified using a template found on the HRA website this is emailed to the REC for categorisation and HRA review.
The sponsor will sign the non-substantial amendment form before submission.
Study amendments can be implemented once regulatory approvals have been granted.

Amendments requiring a new Ethics application:

The submission of a **separate protocol** would always require the submission of a new ethics application.
Generally, where a proposed amendment would fundamentally alter the nature of the research and the extent of the involvement of, or risk to, existing and/or potential participants, the REC may give an unfavourable opinion and request submission of a new application for full ethical review.
Examples might be where the proposed amendment involves:

- A change in the primary purpose/ objective of the research, e.g. Introduction of additional genetic studies.
- A substantial change in research methodology.
- Introduction of new classes of investigations or other interventions (rather than simply re-scheduling or modifying those already approved).
- Recruitment of a new type of participant (especially if these would be regarded as being from vulnerable groups).