Hosted Amendment Guidance

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Introduction

Amendments are changes made to the research after a favourable ethical opinion has been given. They can be 'substantial' or 'non-substantial'. A proposed change to a project will have been reviewed by the research sponsor and classified as either substantial or non-substantial. Once a sponsor has reviewed an amendment and the relevant regulatory approvals have been sought the sponsor will then be responsible for notifying research sites. Research sites will then be responsible for reviewing their capacity and capability to implement the amendment to the study.

It is important to note that, whilst non-substantial amendments do not require REC approval, they do need to be submitted to the HRA for categorisation and, if necessary, assessment. All non-substantial amendments should still be sent to the approving REC committee for notification purposes. The REC will send an acknowledgment of receipt. This document will outline the process for obtaining amendment packs from sponsor and obtaining continued CoC&C from R&D.

Amendment Categories

Amendments can be split into substantial amendments and non-substantial amendments.

A substantial amendment is defined as an amendment to the terms of the application, or to the protocol or any other supporting documentation that is likely to affect to a significant degree:

- The safety or physical or mental integrity of the subjects of the trial
- The scientific value of the trial
- The conduct or management of the trial
- The quality or safety of any investigational medicinal product used in the trial

A non-substantial amendment is defined as having no significant implications for participants or for the conduct, management or scientific value of the study and can be regarded as 'non substantial' or 'minor'. These amendments will generally involve minor clarifications, corrections or changes to contact details.

HRA Categorisation

As part of the HRA review process amendments will be categorised A,B or C:

- Category A amendments affect all sites in the study and require R&D amendment acceptance.
- Category B amendments will only affect certain research sites and will only require R&D amendment acceptance if they affect NuTH as a site e.g. Change of PI at NuTH
- Category C amendments do not require R&D amendment acceptance, however they should still be sent to the trust inbox for storage for audit purposes. An example could be new sites being added that do not affect NuTH or protocol amendments that only involve a typographical error.

Submitting an Amendment to R&D

All amendments must be submitted by email to Trust Research & Development (Nuth.amendments@nhs.net)in the following format:

- All documents required for an amendment should be sent from the sponsor to the site which includes R&D, the local CRN and the delivery team.
- The document pack should include everything required to review and implement the amendment. The delivery team should review the submitted document pack to ensure it contains all required documents. If the pack is invalid the team should inform sponsor of this, request additional documents and make sponsor aware that a 35 day clock has not been started.
- It is the responsibility of the delivery team to assess the capacity and capability of the team to implement this amendment.
- The delivery team should complete a NuTH Hosted Capability Form to inform R&D of the amendment
- The amendment submission should include:
  - Relevant regulatory approvals e.g. HRA, MHRA and REC if required
  - Final versions of the patient documents described in the REC letter e.g. protocol, PIS/ICF
  - Updated IRAS form (if required)

  - Amendment Capability Form – required for all category A amendments, category B amendments that affect NuTH site, or any changes to recruitment timelines/target/actual end date of the study etc.
  - Relevant department approvals e.g. pharmacy/laboratories
  - A revised costing Tool (if the amendment has financial implications)
- Clinical Trial Agreement (CTA) amendment (if changes to CTA).
- All documents must be sent in a zipped folder.
- The subject of the email must be following format: study R&D number – Amendment Ref – DD/MM/YYYY
- If submitting multiple amendments, they must be submitted separately and in the above structured format.

R&D/Finance Review

If your amendment submission is complete and requires R&D review the following will occur:

- Amendment is logged for review on internal spreadsheet.
- Documents are uploaded to REDA.
- If financial changes are required, an officer will send these to finance for their review. An officer will liaise with the team/sponsor regarding any financial queries.
- Finance amendments have two sign offs – initial and final.
- If a contract amendment is present, this can only be signed once costs are finalised.
- An officer will confirm amendment acceptance when all the above is in place.

35 day Implementation guidance.

HRA guidance suggests that host research sites should review amendments within a reasonable time frame. They suggest that if a sponsor has not heard back from a site within 35 days of issuing a valid amendment document set, an assumption can be made that the host site has no objection to the amendment and will implement.

It is the responsibility of the delivery team to ‘stop the 35 day clock’ if they feel that they will not be able to submit to R&D in time or that the amendment contains financial changes that may delay the confirmation.