Amendments to low risk NuTH Sponsored Studies

NJRO-GOV-SOP-009

Contents

1. Background/Introduction

Amendments to research studies are changes, both substantial and minor, made to a research study after original approval from the relevant regulatory bodies. Examples of substantial and non-substantial amendments are given in Appendix 1. It is the responsibility of the study sponsor to classify an amendment as substantial or non-substantial. Amendments can include changes to essential documentation or other aspects of a study design.

2. Purpose

This Standard Operating Procedure (SOP) aims to describe the process for obtaining sponsor approval to amend a study categorised as low risk e.g. excludes CTIMPs, ATMPS or non-CE marked Device Trials. For further information relating to amendments where NuTH acts as a host site, please refer to NJRO-GOV-SOP-008. Please refer to NJRO-REG-SOP-009 for information on NuTH sponsored amendments regarding CTIMPs, ATMPs and non-CE marked Device studies.

3. Scope of Document

This SOP is applicable to all personnel carrying out clinical research where The Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH) act as sponsor for the study and members of NuTH Research and Development Department (R&D) / Research Governance Team (RGT) with responsibility for review of amendments.

4. Definitions

CI	Chief Investigator
CC&C	Continued Capacity & Capability
HRA	Health Research Authority
NJRO	Newcastle Joint Research Office
NSA	Non Substantial Amendment
R&D	Research and Development
REC	Research Ethics Committee
RGT	Research Governance Team
SA	Substantial Amendment

5. Roles & Responsibilities

5.1 CI/study team responsibilities

- Notify the RGT of all planned amendments prior to submission to the regulatory authorities.

- Preparation and submission of documentation required for sponsor review and review of CC&C.

- Ensure amended document pack is distributed to participating sites (in line with HRA guidance)

- Gain the necessary regulatory approvals and CC&C from participating sites, prior to implementation. Where NuTH are a participating site the sponsor review of amendment and CC&C review will be undertaken simultaneously.

5.2 RGT Responsibilities

- The RGT are responsible for reviewing planned amendments for sponsor acceptability, compliance with regulatory standards and identification of risks and hazards to study or study population.

- The RGT are responsible for amendment categorisation in line with HRA guidance (Substantial / Non-substantial)

- Confirming NuTH's CC&C and acceptance of amendment.

6. Procedures

The CI / Study Team will identify where an amendment is required and will use the HRA amendment guide to make an initial judgement on the amendment classification e.g Substantial or Non-Substantial.

6.1. Substantial Amendments (SA)

6.1.1 CI to generate a PDF version of the Notice of Substantial Amendment Form (accessed via IRAS)

6.1.2 CI must send a copy of the following documents to nuth.amendments@nhs.net

- IRAS Notice of Substantial Amendment Form
- Amendment Capability Form (NuTH sponsored)
- Clean and Track Change versions of updated documents
- Copy of updated NuTH costing tool (where required)
- Confirmation of Funder acceptance of proposed changes or confirmation of additional funding (where required)
- Confirmation of NuTH support department backing for proposed amendment (where required)

6.1.3 NuTH RGT / Sponsor review.

- Where the Sponsor is in agreement with the CI's classification i.e. SA and the capability form has been completed thoroughly along with all other relevant forms and submitted, a Sponsor representative will send email confirmation of NuTH's acceptance and authorise the Notice of Substantial Amendment in IRAS.
- If documents are missing or have not been submitted in accordance with this SOP, RGT will notify the CI/Delivery team by email and the amendment will not be processed until the submission is complete.
- If the NuTH sponsor representative considers that the amendment should be categorised as a NSA, the CI will be informed via email and asked to complete the NSA Form and resubmit to nuth.amendments@nhs.net

6.1.4 Once the CI receives confirmation of NuTH's acceptance of the SA, they may proceed to notify the relevant regulatory authorities (REC/HRA).

6.1.5 Once confirmation of regulatory approval has been received the CI study team can implement the amendment at NuTH and request CC&C from other participating organisations.

6.2. Non-Substantial Amendment (NSA)

6.2.1 CI to complete a Notice of Non Substantial Amendment Form (available from HRA website - https://www.hra.nhs.uk/approvals-amendments/amending-approval/)

6.2.2 CI must submit the following documents to nuth.amendments@nhs.net

- NSA Form,
- NuTH sponsored capability form
- Clean and Track change versions of any amended documents

6.2.3 NuTH R&D department / Sponsor representative will review the submission.

- Where the sponsor is in agreement with the classification i.e. NSA and the capability form has been completed properly and all relevant forms have been submitted, sponsor Rep will send email confirmation of NuTH's acceptance.
- If documents are missing or have not been submitted in accordance with this SOP, R&D will notify the CI/Delivery team by email and the amendment will not be processed until the submission is complete.
- If the NuTH sponsor representative considers that the amendment should be categorised as a SA, the CI will be informed via email and asked to complete IRAS Notice of Substantial Amendment Form and resubmit to nuth.amendments@nhs.net

6.2.4 Once the CI receives email confirmation of NuTH's acceptance of the NSA, they must email the NSA form to hra.amendments@nhs.net.

6.2.5 The HRA will issue an email confirming the categorisation of the amendment.

6.2.6 Once HRA categorisation has been received the amendment document pack should be provided to any participating organisations for acknowledgement.

7. References

https://www.hra.nhs.uk/approvals-amendments/amending-approval/

https://www.myresearchproject.org.uk/help/hlpamendmentsresearch.aspx

8. Appendices

Appendix 1 – Examples of substantial and non-substantial amendments

Examples of substantial amendments:

- changes to the design or methodology of the study, or to background information likely to have a significant impact on its scientific value;
- changes to the procedures undertaken by participants;
- changes likely to have a significant impact on the safety or physical or mental integrity of participants, or to the risk/benefit assessment for the study;
- significant changes to study documentation such as participant information sheets, consent forms, questionnaires, letters of invitation, letters to GPs or other clinicians, information sheets for relatives or carers;

- a change of sponsor(s) or sponsor's legal representative;
- appointment of a new chief investigator
- a change to the insurance or indemnity arrangements for the study;
- inclusion of a new trial site (not listed in the original application) in a CTIMP;
- appointment of a new principal investigator at a trial site in a CTIMP;
- temporary halt of a study to protect participants from harm, and the planned restart of a study following a temporary halt;
- a change to the definition of the end of the study;
- any other significant change to the protocol or the terms of the REC application.

Examples of non-substantial amendments:

- minor changes to the protocol or other study documentation, e.g. correcting errors, updating contact points, minor clarifications;
- updates of the investigator's brochure (unless there is a change to the risk/benefit assessment for the trial);
- changes to the chief investigator's research team
- changes to the research team at particular trial sites (other than appointment of a new principal investigator in a CTIMP);
- changes in funding arrangements;
- changes in the documentation used by the research team for recording study data;
- changes in the logistical arrangements for storing or transporting samples;
- inclusion of new sites and investigators in studies other than CTIMPs;
- Extension of the study beyond the period specified in the application form.