# Amendments to Hosted Research

**NJRO-GOV-SOP-008**

## Contents

1. **Background/Introduction**
2. **Purpose**
3. **Scope of Document**
4. **Procedure**
5. **Review and Monitoring**
6. **References**
7. **Appendices**

## 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 research study's arrangements. This Standard Operating Procedure (SOP) relates to obtaining continued confirmation of capacity and capability for an amendment from The Newcastle upon Tyne Hospitals (NuTH) NHS Foundation Trust for amendments to research where NuTH act as a host site. For further information relating to amendments where NuTH acts as sponsor, please refer to SOPs NJRO-GOV-SOP-009 for low risk studies and NJRO-REG-SOP-009 for CTIMP, ATMP and device studies.

### 1.1 Categorisation of Amendments

All amendments are categorised by the Health Research Authority (HRA) when submitted to allow them to be handled in an appropriate manner to the specific amendment. The category of an amendment will be identified in the HRA categorisation email.

| Category: | This category includes any amendment to a research project that has: |
|---|---|
| A | Implications for, or affects, all participating NHS/HSC organisations hosting the research project. |
| B | Implications for, or affects, specific participating NHS/HSC organisations hosting the research project. |
| C | No implications that require management or oversight by the participating NHS/HSC organisations hosting the research project. However the amendment should still be submitted for information.<br><br>*Note - Updated Investigator Brochure (IB; Clinical Trials of Investigational Medicinal Products (CTIMPs) only):*<br>Where the IB update, annual or otherwise, constitutes a non-substantial amendment for REC and MHRA and this is the only amendment (e.g. the update to IB does not give rise to updated pharmacy manual or protocol) the updated IB should not be submitted for categorisation. These amendments will always be category C and they will not be assessed by NHS/HSC if submitted. The IB should be provided to each participating NHS/HSC organisation. |

| | |
|---|---|
| New NHS/HSC site | Where the amendment is to add a new NHS/HSC site to the project, the set-up of this new site should proceed according to the process for local study set-up for the nation where the new site is located. |

## 2. Purpose

This SOP describes the procedure for gaining NuTH confirmation of continued capacity and capability for research studies where amendments to the original research have occurred and NuTH is acting as a research site for the study.

## 3. Scope of Document

This SOP is applicable to all personnel carrying out clinical research where NuTH are a host site for the study. It is also applicable to members of NuTH Research and Development (R&D) department with responsibility for review of amendments.

## 4. Procedure

All amendments and related documentation should be submitted to the NuTH R&D amendments inbox – nuth.amendments@nhs.net

### 4.1 Trust acknowledgement of Substantial Amendments

When the amendment has received relevant regulatory approval, the sponsor should send the NuTH R&D department the relevant document set needed for site level review of continued confirmation of capacity and capability. This document set should include:

- Favourable regulatory approval (for example HRA / REC / CAG / MHRA if applicable)
- Updated documents, including for example;
    - Protocol
    - Patient Information Sheets
    - Informed Consent Forms
    - Other patient documents
- Signed Substantial Amendment Form (IRAS form)

Final Trust acknowledgement of amendment is also dependent on the following conditions:

- Confirmation of continued capacity and capability from local study team and relevant support departments for the amendment – by way of completion of Confirmation of Capacity form.
- Any contract implications being approved by the Joint Research Office and R&D finance in the event of a change to budget or NHS costs. For amendments with a change to NuTH finance, an updated NuTH costing tool should be submitted. **Fully signed contracts need to be in place before amendment can be implemented**.

On successful completion of this process, a Trust confirmation of continued capacity and capability email will be issued. Recipients will include Principle Investigator (PI), local study team, relevant local support departments and sponsor.

***All Urgent Safety Measures (USMs) will be implemented immediately at site but should retrospectively follow the relevant process for substantial amendments*.** **All USMs or USM related queries must be escalated to the Research Management & Governance Manager (or delegate) for review prior to implementation.**

**4.2 Trust acknowledgement of Minor Amendments**

All Minor amendments received from sponsor can be implemented at site immediately.

All minor amendment document packs should be submitted to the NuTH R&D office by either sponsor or the study tem.

The document pack should include the following:

- HRA Non-substantial amendment form
- HRA Categorisation email
- Any updated documents

Following receipt of this document pack the NuTH R&D office will send out an acknowledgement email to the local study team.

**4.3 Change of Local Recruitment Target or Study Timelines**

Should a sponsor wish to change the local study recruitment target or study timelines, NuTH R&D will require the following:

- Confirmation of continued capacity and capability from local study team and support departments (where applicable).
- Updated contract or written confirmation from sponsor of payment terms.

## 5. Review and Monitoring

This SOP will be reviewed every 2 years or in the event of a change to the appropriate regulations. NuTH R&D will monitor the use of this SOP during the audit cycle.

## 6. References

6.1. HRA approval of amendments https://www.hra.nhs.uk/approvals-amendments/
6.2. Amendments for projects conducted in the NHS/HSC – IRAS https://www.myresearchproject.org.uk/help/hlpamendmentsresearch.aspx
6.3. Newcastle Joint Research Office – JRO SOPs https://newcastlejro.com/research/resources/documents/

## 7. 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 affecting its scientific value;
- changes to the procedures undertaken by participants;
- any change relating to 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.

Appendix 2 Flowchart for amendment process in NuTH