Southern Health NHS
NHS Foundation Trust

**STANDARD OPERATING PROCEDURE (SOP)**

**SOP Number: NCP/R&D_005**

**SOP Title: Amendments**

| Role | Name | Signature | Date |
|---|---|---|---|
| **SOP Author** | Kirsty Rogers – Research Facilitator | WET Signature | 10 October 2015 |
| **SOP Reviewer** | Dr Peter Phiri – R&D Manager | Peter Phiri | 22 March 2016 |
| **SOP Authorizer** | Dr Shanaya Rathod – R&D Director | Shanaya Rathod | 05 August 2016 |
| **SOP Review Date** | | | Effective date stamp |

| Version | Effective Date | Review Undertaken/Significant Changes | Date Approved |
|---|---|---|---|
| 1 | 01-Dec-2012 | Initial Version | 28-Aug-2012 |
| 2 | | Template updated to include additional sections and further guidance in preparation of SOPs | |

## 1. PURPOSE AND CONTEXT

This SOP describes the procedure to give Southern Health NHS Foundation Trust (SHFT) approval to an amendment for a research study for which SHFT is a site or sponsor.

## 2. DEFINITIONS

**Amendment –** A written description of a change or formal clarification.

- Please refer to the HRA guidance on what constitutes a substantial amendment and therefore requires review by the main REC http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/preparing-amendments/

- Please refer to the MHRA guidance on what constitutes a substantial amendment and therefore requires review by the MHRA http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/ManagingyourCTA/Amendments/Generalinformation/index.htm

- Where there are amendments to a study that are not required to be submitted to the main REC or the MHRA but that may affect the NHS permission given these should be submitted to the R&D Office in the form of a letter with any accompanying document e.g. Change of Funder/Funding or Change to the local research team.

## 3. PROCEDURE and RESPONSIBILITIES

3.1 Amendments can be reported to the R&D Office of SHFT directly by the research study team or by the CRN.

| | Responsibility | Undertaken by | Activity |
|---|---|---|---|
| 1 | Chief Investigator | R&D Office | Notification of amendment to Research Ethics Committee (REC), and other agencies: Medicines and Healthcare products Regulatory Agency (MHRA), and Clinical Research Network (CRN) for National Institute Health Research (NIHR) adopted studies as appropriate |
| 2 | Principal Investigator | R&D Office | Forward all notifications of amendment (including minor amendments) to the R&D Office for review. |
| 3 | R&D Office | R&D Co-coordinator/ Research Governance Officer | • Collate documentation submitted to REC (Notification of amendment, covering letter, new versions of protocol and other documentation on local headed paper with local investigator team information, REC amendment approval letter )to confirm all documents received. |

| | Responsibility | Undertaken by | Activity |
|---|---|---|---|
| 4 | R&D Office | R&D Manager/R&D Co-ordinator | Assessment of change<br>• Does this involve any material change to running study in SHFT?<br>• If yes – use NCF-R&D_007 – Study Risk Assessment form to assess |
| 5 | R&D Office | R&D Co-ordinator | Check documentation received using NCF-R&D_020 – Amendments Checklist. |
| 5 | R&D Office | R&D Manager | • Where the amendment can be accommodated, issue letter to PI confirming NHS permission of amendment with updated amendment history sheet |
| 6 | R&D Office | R&D Manager | • Where the amendment cannot be accommodated by the Trust the sponsor, Chief Investigator and Principal Investigator must be informed within 35 days of receipt of the amendment and NHS Permission withdrawn from that study in writing. |
| 7 | R&D Office | R&D Co-ordinator/Rsearch Governance Officer | • File letter in Site Master File<br>• Update research database with details of amendment<br>Where necessary note withdrawal of NHS Permission |
| | R&D Office | R&D Administrator /Coordinator | • Log on study NCF-R&D_003 – R&D Log of Approvals and Amendments (Substantial and non-substantial) notify R&D team of approval. |
| | R&D Office | All Staff | • R&D team members to read and understand all applicable documents to the study. |

## 4. SUPPORTING MATERIAL and ATTACHMENTS

The following documents can be used in conjunction with this SOP:-

NCF-R&D_003 – R&D Log of Approval and Amendments (Substantial and non-substantial)

NCF-R&D_007 – Study Risk Assessment Form

NCF-R&D_020 – Amendments Checklist

## 5. TRAINING

5.1 All R&D staff are required to read and understand the content within this SOP. Staff should sign to confirm that the SOP has been read and document this within the R&D SOP file. When the SOP is updated, staff will be notified and will need to re-read and sign against the SOPs within the R&D SOP file.

5.2 As applicable, training will be given in relation to study specific documents and will be documented in the site file.

## 6. REFERENCES

Department of Health Research Governance Framework for Health and Social Care
**http://www.dh.gov.uk/en/Aboutus/Researchanddevelopment/Researchgovernance/DH_4002112**

The Medicines for Human Use (Clinical Trials) Regulations 2004
**http://www.legislation.gov.uk/uksi/2004/1031/contents/made**

The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006
**http://www.legislation.gov.uk/uksi/2006/1928/contents/made**

Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006, Statutory Instrument 2006/2984 **http://www.legislation.gov.uk/uksi/2006/2984/contents/made**

Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008, Statutory Instrument 2008/941

**http://www.legislation.gov.uk/uksi/2008/941/pdfs/uksi_20080941_en.pdf**

Medicines for Human Use (Marketing Authorisations Etc) Amendment Regulations 2008, Statutory Instrument 2008/3097

**http://www.mhra.gov.uk/home/groups/clin/documents/websiteresources/con033682.pdf**

Medicines for Human Use (Advanced Therapy and Miscellaneous Amendments) Regulations 2010, Statutory Instrument 2010/1882
**http://www.legislation.gov.uk/uksi/2010/1882/pdfs/uksi_20101882_en.pdf**