Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Research Department

STANDARD OPERATING PROCEDURE

Project Authorisation

SOP History	*A133 & B129*
SOP Number	*C124*
Created	*STH Research Department (JB)*
Reviewed	*N/A*
Superseded	
Version	*1.0*
Date	*03 June 2013*
Related SOPs	*A116 Investigator site file*
	C108 Sponsorship
Approved by	*Research Manager*

Standard Operating Procedure: STH Research Department

Project Authorisation

This SOP has been produced in accordance with Research Governance Framework 2005, Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments, NIHR CSP Operating Manual and the NIHR Research Support Services Framework. This SOP will outline the procedure for R&D approval of a research project required for a study to commence. This SOP applies to all research involving STH patients, staff, data, tissue or premises at Sheffield Teaching Hospitals NHS Foundation Trust.

Background

The DH Research Governance Framework requires that all organisations providing care ensure that no health or social care research involving human participants, their organs, tissue or data may begin before:

- an identified Sponsor has taken on responsibility for that research
- the study has received a positive ethical opinion, and
- the allocation of responsibilities are agreed and documented.

The organisation must also maintain records of all research undertaken with the participation of the organisation and retains responsibility for all quality of care whether or not aspect of the care are part of a research study.

Definition

NHS R&D approval (or NHS Permission) is the sign off by a member of the Trust Executive Board/Director of R&D to confirm that the research project fulfils all requirements as defined by the Research Governance Framework, relevant legislation and guidelines. NHS R&D approval is the permission that allows study procedures to start within the organisation.

For the purposes of this SOP, IMP studies refers to those studies involving an Investigational Medicinal Product (IMP) which are covered by the Medicines for Human Use (Clinical Trial) Regulations 2004 and subsequent amendments.

Procedure

1. The relevant researcher or Directorate Coordinator completes the STH project registration form and e-mails this to the Research Department Research Facilitator. The Research Facilitator registers the project on the Research Management System (RMS)
   1.1. On registration the study is assigned an STH number, which must be quoted in all future correspondence.
   1.2. The Research Facilitator sends to the local Chief Investigator (CI)/Principal Investigator (PI) a registration confirmation memo by email, providing brief details on the research authorisation process and of the dedicated Research Department R&D Coordinator assigned to the project. The memo is copied to the R&D Coordinator, co-investigators and/or commercial company contact, if details are provided.
2. The R&D Coordinator makes contact with the study team or relevant person (e.g. Directorate Coordinator if applicable) to discuss the study and requirements for R&D approval; requirements will vary dependent on the nature of the study and applicable regulations. The R&D Coordinator proceeds to collate all relevant documentation for the study and appropriate approvals.
3. The R&D Coordinator determines which local approvals are required and proceeds through the R&D approval process, completing RMS simultaneously and uploading to Alfresco accordingly.
4. The STH CI/PI, Directorate Coordinator or other relevant personnel responds to ongoing feedback from the R&D Coordinator regarding outstanding documentation, errors or missing data in a timely manner. The STH CI/PI or relevant representative may contact the R&D Coordinator for clarification and an update on progress at any time.

5. The R&D Coordinator confirms the status of the project and prepares a signed R&D approval letter (or NHS Permission letter) for sending to the PI within 5 working days of receipt of all necessary documentation.
6. On receipt of the R&D approval letter, the STH CI/PI files it in the appropriate section of the Investigator Site File and may start the study.
7. If the study is on CSP then the R&D Coordinator must complete all CSP requirements and update the local CSP Portal on an ongoing basis in line with the NIHR CSP Operating Manual.
8. At the point of R&D approval, the R&D Coordinator ensures all fields in RMS are filled in correctly and appropriately, and all documents have been saved to Alfresco.

For STH Sponsored non-IMP multi-centre studies

9. On confirmation of the study sites, the STH CI provides the R&D Coordinator and where applicable the contracted CTRU/CRO with the details of the local PI and R&D office contact information of the non-STH sites; this should be as early in the process as possible.
10. The CI receives authorisation for the study to start at STH (as above).
11. R&D approval at participating sites must be in place prior to the research site commencing the study; this is the responsibility of the local PI and where applicable facilitated by the contracted CTRU/CRO.
12. The R&D Coordinator will ensure a contract is in place with participating sites if applicable.
13. The CI files a copy of each authorisation letter in the CI Investigator Site File (Trial Master File).
14. The PI files a copy of their authorisation letter in their Investigator Site File.

For STH Sponsored CTIMPs

15. For STH Sponsored CTIMPs, the above steps are followed.
16. In addition, for each site participating in an STH sponsored CTIMP there must be:
    - an appropriate contract in place outlining roles and responsibilities.
    - the participating site PI CV and GCP certificate.
    - a signed PI responsibilities document

    For a single centre study the R&D Coordinator collates the above documentation. For multicentre studies the CTRU/CRO collate the above documentation. In both cases the CI or delegate files a copy of the documentation in the Trial Master File

Appendix 1
STH Related Documents

	Document	Research Department Network Location	Website	Database	Created by
1	Investigator site file template	Directory\Research Governance\Project Authorisation\Templates\Site file index	Yes	No	TL
2	Authorisation letter template	Directory\Research Governance\Project Authorisation\Templates\authorisation letter	No	No	AL
3	RMS Process manual	S:\General\Research Governance\Project Authorisation\Guidance\Authorisation checklist\RESEARCH GOVERNANCE PROCESS MANUAL.docx	No	No	JB