Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Research Department

STANDARD OPERATING PROCEDURE

Sponsorship

SOP History	*None*
SOP Number	*C108*
Created	*STH Research Department (PC)*
Reviewed	*STH Research Department (EW & AP)*
Superseded	*1.2, 15 November 2006*
Version	*2.0*
Date	*05 Nov 2013*
Related SOPs	*B103 STH Scientific Review* *B106 Execution of Clinical Trial agreements (CTA) for commercially Sponsored Clinical Trials* *B122 R&D Master File* *B124 Execution of Clinical Trial Agreements for non-commercially sponsored trials* *C104 Indemnity for Research,* *C118 Risk Assessment of STH sponsored CTIMPs*
Approved by	*Research Manager*

Standard Operating Procedure: Sponsorship

This SOP has been produced in accordance with Medicines for Human Use (Clinical Trials) Regulations 2004 & subsequent amendments, and the Department of Health's Research Governance Framework 2005. This SOP will outline the procedure for submitting a research project for a sponsorship decision. This SOP applies to all research studies undertaken at Sheffield Teaching Hospitals NHS Foundation Trust (STH).

Background

The Sponsor is responsible for ensuring that the proposed research respects the dignity, rights, safety, and well being of participants. The DH Research Governance Framework requires that all research projects must have a Sponsor identified and declared prior to the commencement of the project.

In addition, under the Medicines for Human Use (Clinical Trials) Regulations 2004 all research projects involving the use of Investigational Medicinal Products (IMPs) must have the Sponsor declared to the Competent Authority. In the UK the Competent Authority is the Medicines and Healthcare Products Regulatory Agency (MHRA).

Definition

The Sponsor is the individual organisation or group taking on responsibility for securing arrangements to initiate, manage and finance a study. STH does not allow an individual to take on the responsibility of Sponsor.

The key responsibilities of a Sponsor, as outlined by the Department of Health, are

- Authorisation arrangements prior to study start
- GCP for conduct, monitoring and reporting of the study
- Pharmacovigilance.

A Sponsor can delegate responsibilities to other parties for which they remain ultimately responsible. Where there is delegation of responsibility, clear agreements describing allocation of responsibilities and rights must be reached, documented and enacted.

The STH Sponsorship Principles Document, as derived from DH guidelines, outlines the Sponsor's responsibilities in relation to STH research studies including the arrangement for provision of indemnity, monitoring and audit of the study.

Procedure

1. The Chief Investigator (CI) or Principal Investigator (PI)[1] registers the proposed project and initial details with STH Research Department, Research Governance Facilitator (RGF).
2. The RGF refers the CI/PI to their assigned R&D Coordinator.
3. The CI/PI submits a study outline / draft grant application / protocol to the R&D Coordinator.
4. For studies where STH is the lead NHS institution, the R&D Coordinator identifies the Sponsor of the research project using the Sponsorship Decision Chart.
   4.1. If the study involves STH patients STH will normally be the sponsor as per the Sponsorship Decision Chart. Where the CI has named their employing university as sponsor the R&D Coordinator makes enquiries to ascertain whether there is a reason why STH should not act as sponsor. Where no reason is determined the R&D Coordinator confirms that sponsorship should be reassigned to STH.

[1] The investigator who takes primary responsibility for the overall conduct of a study is the Chief Investigator. The investigator who takes responsibility for the conduct of a clinical study at an individual site is the Principal Investigator. In relation to a clinical study conducted at a single site the investigator may be referred to as both Chief and Principal Investigator.

4.2. If the study involves an IMP STH must be the Sponsor. The R&D Coordinator contacts the CI to confirm.

4.3. If sponsorship is allocated to STH a letter confirming sponsorship is not issued unless requested by the CI/PI. Acceptance of sponsorship is confirmed by sponsor signature on the REC and/or R&D form.

4.3.1. In the case of a CTIMP potentially sponsored by STH sponsorship cannot automatically be assumed. The R&D Coordinator follows the Risk Assessment of STH Sponsored CTIMPs SOP (C118) to establish whether STH can agree to Sponsorship.

4.3.2. The R&D Coordinator identifies the Sponsor on the Research Database and files an electronic copy of the signed REC and/or R&D form in Alfresco.

4.4. If sponsorship is allocated to an institution other than STH e.g. University of Sheffield (UoS) or Sheffield Hallam University (SHU):

4.4.1. The R&D Coordinator informs the CI/PI of the institution likely to be the Sponsor.

4.4.2. The CI/PI contacts the institution identified as likely to be the Sponsor of the study for confirmation

4.4.3. The CI/PI sends the R&D Coordinator documentary evidence (in most cases the sponsor signed NHS REC or NHS R&D Form) of the external Sponsor and files a paper copy in the Investigator Site File.

4.4.4. The R&D Coordinator enters sponsorship status on the Research Database and files an electronic copy of the evidence provided in Alfresco.

5. For studies where STH is not the lead NHS institution, the assignment of sponsorship will be determined by the lead site. The R&D Coordinator determines the study sponsor using information from the REC/R&D form or mNCA and enters the sponsorship status on the Research Database. The R&D Coordinator files an electronic copy if the signed REC/R&D form or other evidence of sponsorship in Alfresco.

6. The R&D Coordinator then follows the process described below depending whether STH or another institution is the sponsor.

7. **STH sponsored study (STH, UoS or SHU CI)**

7.1. For studies involving an Investigational Medicinal Product (IMP) the R&D Coordinator follows the Risk Assessment of STH Sponsored CTIMPs SOP (C118)

7.2. For non-IMP studies the R&D Coordinator determines whether ISR is required (see STH Scientific Review SOP (s)).

7.3. Acceptance of sponsorship is documented by STH sponsor signature on the NHS REC form.

7.4. For multicentre studies an agreement with participating sites will be required if funding is to be transferred to the participating sites. Where no funding is to be transferred the R&D Coordinator determines the type of study to decide whether an agreement with participating sites is required[2]. The R&D Coordinator consults with a senior member of the Research Department if it is unclear whether an agreement should be required. If an agreement is required, the mNCA is implemented:

7.4.1. The R&D Coordinator completes the mNCA, indicating where an area of responsibility is delegated to another participating site. The R&D Coordinator reviews the proposal with a senior member of the Research Department, as appropriate. The R&D Coordinator sends the CI the mNCA (for review only).

7.4.2. The R&D Coordinator contacts the Research Office of each participating site to negotiate agreement and signature of the mNCA; where a Study project manager is identified, they may facilitate this process.

7.4.3. The mNCA is signed by the STH Director of R&D or delegate and authorised signatory at the participating site.

7.4.4. The R&D Coordinator files the signed agreement according to SOP B122 R&D Master File.

7.5. The R&D Coordinator determines whether any other agreements with external institutions involved in the study (not in the capacity of a participating site) are necessary. The R&D Coordinator consults with a senior member of the Research Department if it is unclear whether an agreement should be required. For CTIMPs agreements with all external

[2] Studies which involve questionnaires, focus groups or interviews are examples of studies that do not require a sponsorship agreement. Studies which are clinical trials of any type of intervention or which involve investigations of an interventional nature generally will require a sponsorship agreement.

institutions involved will generally be required as described in Risk Assessment of STH Sponsored CTIMPs, SOP (C118).

7.5.1. The R&D coordinator contacts the contracts office of the external institution to negotiate an agreement which will indicate clearly what responsibilities are to be undertaken by the external institution.

7.5.2. The agreement is signed by the STH Director of R&D or delegate and authorised signatory at the external institution.

7.5.3. The R&D Coordinator files the signed agreement according to SOP B122 R&D Master File.

7.6. On authorisation the CI receives an NHS Permission letter which details the name of Sponsor and the sponsorship documents and agreements present in the R&D Master File .

8. **Non-commercial, multi-centre study where an external institution is the Sponsor**

8.1. The PI submits evidence of the lead institution's acceptance of sponsorship (eg signed REC application, sponsorship letter).

8.1.1. For studies involving an IMP the Sponsor or legal representative must be located within the European Economic Area (EEA).

8.1.2. For non-CTIMPs with a non-UK sponsor there must be a legal representative in the UK

8.2. The R&D Coordinator liaises with the study sponsor to determine whether the sponsor intends to offer a sponsorship agreement (mNCA where possible).

8.2.1. If the external sponsor does not propose to offer a sponsorship agreement the R&D Coordinator determines the type of study to decide whether to seek an agreement (mNCA where possible) from the sponsor. The R&D Coordinator consults with a senior member of the Research Department if it is unclear whether an agreement should be required. If an agreement is required, use of the mNCA is requested.

8.2.2. For studies involving an IMP an agreement on Sponsorship responsibilities must be in place before authorisation.

8.3. Where an agreement is required (either by the sponsor or by STH Research Department based on the type of study) the R&D Coordinator reviews and negotiates the proposed agreement (preferably the mNCA) with the Sponsor. If the external Sponsor wishes to delegate any of the sponsorship responsibilities to the STH Research Department, detail of this must be contained within the agreement. The R&D Coordinator reviews the proposal with a senior member of the Research Department, as appropriate. An agreement must be reached before authorisation.

8.3.1. If the sponsor does not wish to use the mNCA, the institution's sponsorship agreement is reviewed against the mNCA for consistency and capture of key information.

8.3.2. The sponsorship agreement is signed by the external Sponsor and Director of R&D at STH (or authorised delegate).

8.4. The study sponsor may wish to delegate sponsorship responsibilities to the PI team. The study sponsor is responsible for documenting the delegation of any such arrangement and ensuring the relevant parties are aware of their responsibilities.

8.5. For IMP studies where the study is not managed by a CTRU registered with the UKCRC CTU Network:

8.5.1. The R&D Coordinator requests a copy of the sponsor's study management arrangements or study monitoring plan for review. Where no documented monitoring arrangements exist the R&D Coordinator requests that the sponsor completes the Multi-Centre Study Management Arrangements form.

8.5.2. The R&D Coordinator reviews the plans for sponsor study monitoring to ensure the sponsor has adequate plans for study oversight. The R&D Coordinator discusses the proposed monitoring plan with the QA Lead or Research Manager if there is doubt about the adequacy of the planned sponsor study monitoring.

8.5.3. Where sponsor monitoring plans appear to be inadequate the R&D Coordinator queries and negotiates the arrangements with the sponsor.

8.6. The R&D Coordinator enters sponsorship status onto the Research Database and files a paper copy of the sponsorship agreement in the R&D Master File.

8.7. The R&D Coordinator files the signed agreement according to SOP B122 R&D Master File.

8.8. On authorisation the PI receives an NHS Permission letter which details the name of Sponsor and the sponsorship documents present in the R&D Master File.

9. **Non-commercial, no-local investigator study, where an external institution is the Sponsor**

9.1. The local contact/lead institution contact submits evidence of the lead institution's acceptance of sponsorship (eg signed REC application, sponsorship letter).

9.2. The R&D Coordinator liaises with the study sponsor to determine whether the sponsor intends to offer a sponsorship agreement (mNCA where possible).

9.3. Where an agreement is required by the sponsor the R&D Coordinator reviews the proposal and negotiates an agreement on delegated tasks (mNCA where possible). An agreement must be reached before authorisation.

9.3.1. The sponsorship agreement is signed by the external Sponsor and Director of R&D at STH (or authorised delegate).

9.3.2. The R&D Coordinator files the signed agreement according to SOP B122 R&D Master File.

9.4. On authorisation the CI and local contact receives an NHS Permission letter which details the name of Sponsor and the sponsorship documents present in the R&D Master File.

10. **Commercial studies where the commercial company is the Sponsor.**

10.1. The Sponsor or CI/PI submits the draft contract Clinical Trial Agreement (preferably the model Clinical Trial Agreement (mCTA)) to the R&D Coordinator. The commercial company is identified as Sponsor in the mCTA/contract and all subsequent documentation.

10.1.1. For studies involving an IMP the Sponsor or legal representative must be located within the European Economic Area (EEA).

10.1.2. For non-CTIMPs with a non-UK sponsor there must be a legal representative in the UK

10.2. The R&D Coordinator negotiates agreement on the mCTA and organises the appropriate signatures. The agreement is signed by the external Sponsor and Director of R&D at STH (or authorised delegate).

10.3. The R&D Coordinator files the signed agreement according to SOP B122 R&D Master File.

10.4. On authorisation the CI/PI receives an NHS Permission letter which details the name of Sponsor and the sponsorship documents present in the R&D Master File.

Appendix 1
STH Related Documents

	Document	Research Department Network Location	Website	Database	Created by
1	Sponsorship Decision Chart	Directory\Research Governance\Sponsorship\Templates	Yes	No	BZ
2	Sponsorship Confirmation letter	Directory\Research Governance\Sponsorship\Templates	No	No	BZ
3	Multi-Centre Study Management Arrangements template	Directory\!_Working Drafts\Research Governance\Monitoring documents\Research Department Monitoring Requirements	Yes	No	BZ