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Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Research Department

STANDARD OPERATING PROCEDURE

Clinical Trial Agreements (CTA) for Non-Commercially Sponsored Trials

SOP History	*Version 1.0, 06 July 2011*
SOP Number	*C121*
Created	*Research Department (GMcV)*
Reviewed	*Research Department (JB)*
Superseded	*1.0, 06 July 2011*
Version	*2.0*
Date	*23 July 2013*
Related SOPs	
Approved by	*Research Manager*

Standard Operating Procedure

Execution of Clinical Trial Agreements (CTA) for Non-Commercially Sponsored Clinical Trials

This SOP has been produced in accordance with the Research Governance Framework. This SOP will outline the procedures involved in the agreement and signature of the Clinical Trial Agreement (CTA) for non-commercially sponsored research studies conducted within Sheffield Teaching Hospitals (STH) NHS Foundation Trust.

Background

All non-commercially sponsored research involving an investigational medicinal product or a device carried out at Sheffield Teaching Hospitals NHS Foundation Trust must have a fully executed non commercial clinical trial agreement or sponsorship agreement in place before the study starts. Both the study Sponsor and the Participating Site must sign a written agreement that formalises the responsibilities between the Parties for the conduct of the trial. This agreement must define the scope of work, establish acceptable payment arrangements, and address important issues such as the right to publish research results, protection of confidential information, and indemnification of third parties and/or case injury.

The UKCRC (UK Clinical Research Collaboration) has developed a Model Agreement for Non Commercial Research in the NHS (the mNCA) in 2008. This is a standard contractual framework for non commercial trials involving NHS patients (Appendix 2). The mNCA is the preferred contract of choice in STH NHS FT to be used for non-commercially sponsored studies conducted within the Trust. Some NHS Trust and Universities may have developed their own template agreement for use in non-commercial trials which they sponsor. Such templates are acceptable to STH if they follow the same principles as the mNCA and clearly define the roles and responsibilities of each Party to the agreement.

Definition

The Model Agreement for Non Commercial Research in the NHS (mNCA) is a document to outline the contractual responsibilities between 2 or more persons/institutions for the conduct of a clinical trial or research study.

The R&D Coordinators in the Research Department are responsible for negotiating and executing mNCAs at STH NHS FT; individual investigators are not permitted to enter into contractual agreements on behalf of the Trust.

Procedure

1. The Principal Investigator (PI) registers the project with the Research Department and forwards the Protocol, draft mNCA received from the study Sponsor to their R&D Coordinator.

2. The R&D Coordinator will review the mNCA for content.
   2.1. If the non commercial sponsor is providing payment to STH for its involvement in a trial, the mNCA will be forwarded to the STH Research Accountant for their review and approval.

3. The R&D Coordinator reviews the mNCA and corresponds with the Sponsor to gain agreement on the content of the mNCA with the assistance of the STH Contracts Lead for the Research Department, the Trust Solicitor and/or Trust Corporate Governance Department where necessary.

4. The R&D Coordinator will request the use of the mNCA where possible in particular if there is not a Sponsor agreement available or if this is unsuitable.

5. Principal investigators who are STH Trust substantive contract holders

   5.1. The R&D Coordinator establishes whether the trial has been adopted on the NIHR portfolio of research and is eligible for obtaining support costs from the local Comprehensive Local Research Network (South Yorkshire CRLN).
   5.2. The R&D Coordinator informs the STH Research Accountant of the portfolio status of the trial and whether any funds are being paid directly from the Sponsor to STH.

5.3. The STH Research Accountant with assistance from the R&D Coordinator contacts the PI and STH support departments to confirm that all costs associated with the protocol are covered. The costs will include appropriate Trust overheads and Research Governance charges (if applicable), STH support department costs (service support costs if portfolio adopted), excess treatment costs and PI/research nurse time.
5.3.1. Where STH is a participating site, the STH Research Accountant agrees the study service support costs with the local CLRN for portfolio adopted trials and with the Sponsor if funds are being paid to STH directly.
5.3.2. For non portfolio trials, the STH Research Accountant will agree costs with the study Sponsor only.
5.4. The STH Research Accountant reviews the Financial Schedule of the agreement to include all Trust costs (as agreed above), details of payment terms, Trust Bank Account, Trust research account reference and Trust contact and address for invoicing if applicable.

6. Principal investigators who are University of Sheffield substantive contract holders

6.1. The R&D Coordinator establishes whether the trial has been adopted on the NIHR portfolio of research and is eligible for obtaining support costs from the local Comprehensive Local Research Network (South Yorkshire CRLN).
6.2. The R&D Coordinator informs the STH Research Accountant of the portfolio status of the trial and whether any funds are being paid directly from the Sponsor to STH or whether funds are to be paid to and managed by the University of Sheffield.
6.3. The R&D Coordinator contacts the PI, STH support departments and the University Non Commercial Research Manager to arrange a set up meeting(s) or telecon(s) to confirm that all costs associated with the protocol are covered. The costs will include appropriate Trust and University overheads and Research Governance charges (if applicable), PI time/Research Nurse time, STH support department costs (service support costs if portfolio adopted), excess treatment costs.
6.3.1. The STH Research Accountant agrees the study costs with the CLRN for portfolio adopted trials and with the Sponsor if funds are being paid to STH directly.
6.3.2. For non portfolio trials, the STH Research Accountant will agree costs with the study Sponsor and PI employer.
6.4. The PI completes, with the help of their Department Manager or equivalent, the University Research Management System (URMS) Form detailing the cost of their time to be spent on the study and forward the completed URMS form to their Head of Department and the University Non Commercial Research Manager for their approval.
6.5. The STH Research Accountant revises the Financial Schedule in the trial agreement to include all Trust and University of Sheffield costs (as agreed above), details of payment terms, Trust Bank account, Trust research account reference and Trust contact and address for invoicing if applicable; if funds are to be paid to and managed by the University of Sheffield, the appropriate details are provided.
6.6. The STH Research Accountant informs the R&D Coordinator that the financial arrangements are agreed and confirms the University fee.

7. The STH Research Accountant electronically approves the applicable finance task in the Research Department Research Management System confirming that costs included in the STH Finance Form and mNCA Financial Schedule are agreed.

8. On agreement of the mNCA wording and financial arrangements, the R&D Coordinator requests three signed copies of the mNCA from the Sponsor contact and arranges signature of the mNCA by the Director of Research or other approved signatory.

9. The R&D Coordinator returns one copy of the fully executed mNCA to the Sponsor, a second copy to the PI for the Investigator Site File and a final copy is retained in the R&D Project Master File. The R&D Coordinator ensures a copy of the fully signed agreement along with the final finance form and signed R&D authorisation letter are uploaded onto the Alfresco document repository.

10. Where the PI is a University of Sheffield employee:
10.1. The STH Research Accountant completes specific Collaboration Agreement Side Letter (Appendix 3). The R&D Coordinator arranges Trust and University sign off of two copies of

this document, ensuring the Trust and University of Sheffield Non-Commercial Contracts Manager have a final approved copy. The Side Letter details the amount of funds to be transferred to the University for the PI participation in the study. The R&D Coordinator sends a photocopy of the signed study specific Collaboration Agreement Side Letter to the PI for the Investigator Site File. Where funds are being managed by the University and are to be transferred from the University to STH, the Contracts Manager at the University sends a Side Letter signed by the University to the R&D Coordinator who will obtain the Trust signature. The final approved side letter is placed on the Alfresco document repository with the wet ink copy filed in the R&D Project Master file.

11. Where the PI is a Sheffield Hallam University employee:
    11.1. Where required, the STH Research Accountant uses the specific Collaboration Agreement Side Letter (Appendix 3) amended to reflect Sheffield Hallam University. The R&D Coordinator arranges Trust and University sign off of two copies of this document, ensuring the Trust and University have a final approved copy. The Side Letter details the amount of funds to be transferred to the University for the PI participation in the study. The R&D Coordinator sends a photocopy of the signed study specific Collaboration Agreement Side Letter to the PI for the Investigator Site File. Where funds are being managed by the University and are to be transferred from the University to STH, the Contracts Manager at the University sends a Side Letter signed by the University to the R&D Coordinator who will obtain the Trust signature. The final approved side letter is placed on the Alfresco document repository with the wet ink copy filed in the R&D Project Master file.

12. On final project R&D authorisation, the R&D Coordinator updates the Research Management System with the final agreed funds coming to STH.

13. The STH Research Accountant reviews the Research Management System on a regular basis to ensure that all authorised projects have invoicing arrangements in place and are receiving funding as agreed.

Appendix 1 - Associated Documents

	Document	Research Department Network Location	Website	Created by
1	STH Finance form	Directory\Research Governance\Project Authorisation\Templates	Yes	KM
2	Authorisation letter	Directory\Research Governance\Project Authorisation\Templates\authorisation letter	No	TL
4	University of Sheffield Collaboration Agreement Side letter	Directory\Research Governance\Project Authorisation\Templates	No	University Research Office/JP

Appendix 2 - Model Agreement for Non Commercial Research in the Health Service

National template
http://www.ukcrc.org/regulationgovernance/modelagreements/mnca/

Appendix 3: University Side Letter

CLINICAL TRIAL – SIDE LETTER

[Address of non-lead organisation]

Dear [name]

[PROJECT TITLE]
[FUNDING BODY / AWARD REFERENCE NUMBER]

This Side Letter is issued in accordance with Clause 4.5.1 of the Collaboration Agreement between The University of Sheffield ("University") and Sheffield Teaching Hospitals NHS Foundation Trust ("Trust") dated [date].

The [FUNDING BODY] ("Funding Body") has entered into an agreement ("Funding Agreement") attached as Annex 1 with [FUNDING HOLDER, (the University or the Trust)] in respect of the above titled project ("Project").

The Principal Investigator for the Project is [NAME OF PI] at [University/Trust]. The parties to this letter agreement are referred to as "Collaborators", or a "Collaborator" as the case may be.

The trial will be administered by [LEAD ORGANISATION]. A copy of the trial authorisation is attached at Annex 2. The terms and conditions of the Collaboration Agreement along with the terms of the Funding Agreement will govern the conduct of the trial. In the event of a conflict between the terms of the Funding Agreement and the Collaboration Agreement, the terms of the Funding Agreement shall prevail.

The start date is _XXXX___ for a period of _XXX months, contingent on the trial starting as described in the protocol and Funding Agreement.

The Parties shall perform the tasks envisaged in the protocol as approved by the Funding Body, or as may be agreed from time to time between the Collaborators.

Issues relating to Intellectual Property, Confidentiality, Publications and Publicity shall be managed in accordance with Clauses 6 and 7 of the Collaboration Agreement and the relevant sections of the Funding Agreement. The terms of the Funding Agreement shall take precedence.

The [FUNDING RECIPIENT] shall provide reports to the [FUNDING HOLDER] for the [FUNDING HOLDER] to fulfil its obligations to the Funding Body in accordance with the Funding Agreement.

[FUNDING HOLDER] will forward to [FUNDING RECIPIENT] up to the total sum of £_XXX____ towards the cost of its contribution to the Project as further detailed in Annex 3, subject always to receipt by [FUNDING HOLDER] of the funds from the Funding Body. [FUNDING RECIPIENT] will invoice the [FUNDING HOLDER] according to the payment schedule in Annex 3 and [FUNDING HOLDER] shall pay [FUNDING RECIPIENT] within thirty (30) days of receipt of said invoice. The final invoice will be sent by [FUNDING RECIPIENT] to [FUNDING HOLDER] within two (2) months of the end of [FUNDING

RECIPIENT]'s involvement in the trial to allow preparation of any final cost statements by [FUNDING HOLDER].

In the event that the Funding Body requires the reimbursement by [FUNDING HOLDER] of any sums paid under this Side Letter, then to the extent that such requirement arises from the acts or omissions of [FUNDING RECIPIENT], [FUNDING RECIPIENT] hereby agrees to reimburse the [FUNDING HOLDER] the sum received by [FUNDING RECIPIENT] together with any interest charged thereon.

Invoices should be sent to:
[FUNDING HOLDER]
Finance office / Department

quoting reference _____.

I should be grateful if you would confirm that you are happy to accept [FUNDING RECIPIENT]'s share of the grant on the above terms by signing and returning a copy of this letter to me at the above address.

Accepted on behalf of [FUNDING HOLDER]	Accepted on behalf of [FUNDING RECIPIENT]
Signature:	Signature:
Name/position:	Name/position:
Date:	Date:

cc: Chief Investigator
Principal Investigator

Annex 1 – Funding Agreement

Annex 2 – Study authorisation

Annex 3 – Budget and Payment Schedule