York Foundation Trust R&D Unit
Standard Operating Procedure
R&D/S23

Contracts for Clinical Trials of Investigational Medicinal Products

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Unit's website and R&D Newsletter for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: www.northyorksresearch.nhs.uk/sops.html

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Author:	Damon Foster
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Approved by:	Name/Position:	Deborah Phillips, Research Adviser
	Signature:	Signed copy held by R&D Unit
	Date:	7th October 2014
	Name/Position:	Sarah Sheath, SOP Controller
	Signature:	Signed copy held by R&D Unit
	Date:	7th October 2014

This SOP will normally be reviewed every 2 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	11th January 2010	
2.0	5th December 2011	Change of SOP Controller. Inclusion of University of York in procedure. Removal of CTIMP from SOP reference
3.0	10th November 2014	Change of author. Removal of references to North and East Yorkshire Alliance.

Contents

1 Introduction, Background and Purpose

This SOP establishes a procedure for putting in place suitable contracts for clinical trials of investigational medicinal products (CTIMPs) in the Trust to support compliance with the UK Clinical Trial Regulations and organisational governance.

The term 'contract' is used in this document as a generic term and includes documents described as 'Agreements'

2 Who Should Use This SOP

This SOP is aimed at:

- R&D Unit personnel who are responsible for drafting, negotiating or approving contracts relating to the conduct of CTIMPs, whether these are:
    - sponsored or co-sponsored by the Trust; or
    - sponsored by external organisations and hosted in the Trust
- Staff in the North and East Yorkshire and Northern Lincolnshire Comprehensive Local Research Network (CLRN) who are involved in the process of obtaining NHS Permission for conduct of a CTIMP in the Trust;
- Chief or Principal Investigators for CTIMPs to be sponsored or hosted in the Trust or the University of York;
- Staff of the University of York which has contracted to use R&D Unit SOPs for conduct of CTIMPs; in particular, Research Innovation Office personnel who are responsible for drafting, negotiating or approving contracts relating to the conduct of CTIMPs,

This SOP also contains information that will be useful for external organisations wishing to enter into CTIMP-related contracts with the Trust or the University of York.

3 When this SOP Should be Used

This SOP should be used whenever sponsorship or hosting of a CTIMP in the Trust or the University of York is being arranged.

4 Responsibilities and Contract Signature Arrangements

4.1 Responsibilities of the R&D Unit

The R&D Unit will represent the Trust in relation to all contracts required in connection with Trust **sponsorship or co-sponsorship** of a CTIMP.

Contracts for CTIMPs to be **hosted** in the Trust should never be negotiated or signed by members of staff without the involvement of the R&D Unit.

Within the R&D Unit the R&D Manager has primary responsibility for contract management.

4.2 Responsibilities of the University of York Research Innovation Office

The Research Innovation Office will represent the University of York in relation to all contracts required in connection with University of York **sponsorship or co-sponsorship** of a CTIMP.

Contracts for CTIMPs to be hosted / have services provided in the University of York should never be negotiated or signed by members of University staff without the involvement of the Research Innovation Office.

Within the Research Innovation Office the Intellectual Property Manager has primary responsibility for CTIMP contract management, assisted by the Contracts Officer.

4.3 R&D Unit and Research Innovation Office responsibilities for co-sponsorship arrangements

In relation to co-sponsorship arrangements between the Trust and the University of York, the R&D Unit and the Research Innovation Office will work collaboratively to ensure that the trial is set up in accordance with the Standard Operating Procedures and the requirements of the York Teaching Hospital NHS Foundation Trust Research and Development Group, and that the interests of both the co-sponsoring organisations are protected.

4.4 Signature of CTIMP contracts

The Trust's research contract signatory(ies) in order to ensure compliance with its internal governance arrangements is, in default, the Chief Executive Officer

The R&D Unit will send CTIMP contracts to the appropriate signatory with a covering memorandum based on the template referenced in Section 7 and printed on coloured paper. In order to ensure that research contracts are only signed following appropriate R&D Unit review, contracts should only be signed in response to a request from the R&D Manager in the form of this memorandum.

All CTIMP contracts will be signed on behalf of the University of York by the Director of Research & Enterprise or the Intellectual Property Manager in the Research Innovation Office.

Neither individual members of staff of the Trust or the University of York, nor individual Trust or University Departments, should be parties in research contracts; Principal Investigators or Heads of University Departments providing CTIMP services may be asked to sign such contracts to acknowledge that they have read them, but they should never sign as parties.

For the avoidance of doubt, a partial exception to this is the Memorandum of Understanding used in connection with the running of studies in the York Clinical Research Facility (YCRF). This records an agreement about how investigator teams will work in collaboration with the YCRF and its staff, and is to be signed by the YCRF Co-ordinator and the study's Chief / Principal Investigator. It does not stand alone as a legally – binding contract. In all cases where staff or facilities external to York Teaching Hospital NHS Foundation Trust are involved there will be additional formal contract(s), managed in the usual way, and the

Memorandum will be referenced so as to incorporate this in the formal contract structure.

5 Contract planning and drafting

5.1 Initial Contract Planning Meeting

At the earliest stage (in the case of a study required to be submitted for sponsorship or co-sponsorship to the York Teaching Hospital NHS Foundation Trust Research and Development Group, this means as soon as the proposed trial has passed its 'feasibility review') the Chief Investigator should request a meeting to discuss contract requirements, as follows:

Contact the R&D Unit's R&D Manager if the study:

- Is proposed for sole sponsorship by the Trust;
- Is proposed for co-sponsorship by the University of York and the Trust.

Contact the Intellectual Property Manager in the University's Research Innovation Office if the study:

- Is proposed for co-sponsorship by the University of York and another organisation outside the Trust.

R&D Unit and Research Innovation Office staff will liaise with each other as required and may arrange a joint meeting if this is appropriate.

5.2 Identification of required contracts

The main purpose of this meeting is to identify all required contracts. This should include any organisation or individual consultant outside the proposed sponsor(s) that will be involved in the trial in any way. The following list of possible contracting parties is illustrative and not exclusive:

- An organisation that will manufacture and / or supply the investigational medicinal product (IMP);
- Organisations responsible for pharmacy, laboratory, radiology or similar services being provided for the trial;
- Clinical Research Organisations or Consultants being engaged to carry out monitoring or data management services for the trial.

5.3 Dealing with contracting parties

Part of the planning at this initial meeting will be to clarify the involvement of the R&D Unit and/or Research Innovation Office and allocate tasks. Following the meeting the R&D Unit and / or Research Innovation Office will establish communication with appropriate representatives of contracting parties and conduct contract negotiations. In doing so, they will consult involved members of the proposed sponsor(s) staff as appropriate – including the Chief Investigator and representatives of key support departments such as NHS Pharmacy, NHS or University Laboratories, NHS Radiology, University Trials Unit / Data Management.

Where contracted services are to be provided by external organisations, for example IMP supply or laboratory tests, appropriate evidence of competence to carry out the services will be obtained from them. This may take the form of accreditation or inspection evidence or other suitable evidence as the R&D Unit /

Research Innovation Office may determine, if necessary with the benefit of advice from senior colleagues in relevant specialist departments.

Where services are to be provided by an external commercial company or consultant on a full payment basis contractors will be chosen in accordance with the relevant tendering and other procedures of the sponsoring organisation; the R&D Unit will liaise with appropriate members of the Trust's staff to ensure that these arrangements are correctly made.

5.4 Contract drafting

The R&D Unit and/or the Research Innovation Office as appropriate will base draft contracts on the templates referenced in Section 7, with modifications as required for contractual certainty and clarity of understanding between the parties.

Where other parties, such as service provider companies, have their own standard contracts, their drafts may be used as an alternative, provided that, in the judgement of the R&D Unit and/or the Research Innovation Office these are clear, cover all relevant matters and place no unduly onerous obligations on the sponsoring organisation(s).

For contracts with trial sites the relevant National Model Clinical Trial Agreement will be used, with the following approach to modifications:

- Generally as few modifications as possible will be made – only those that are required to make the document a full and accurate agreement about the work to be conducted;

- The Schedule of Responsibilities will be used with some standard amendments, as in the relevant template referenced in Section 7.

In the event that a particular trial has very unusual contracting requirements the R&D Unit and / or Research Innovation Office may seek the legal advice in accordance with the usual arrangement for this within their organisations.

6 Contracts relating to CTIMPs sponsored by external organisations

The responsibilities of the R&D Unit and/or Research Innovation Office and the signature arrangements set out in Section 4 above apply in this situation.

In all cases where the Trust is being asked to be a trial site, an appropriate contract must be put in place. The draft offered by the Sponsor will be reviewed and negotiated by the CLRN and/ or the R&D Unit as part of the NHS Permission application, in accordance with the relevant SOP referenced in Section 7.

There should be one contract for each trial site – separate agreements made with individual departments such as the site's pharmacy, or with individual members of staff, are unacceptable.

To be acceptable the draft contract should be based on the appropriate National Model Clinical Trial Agreement as published by the UK Clinical Research Collaboration (www.ukcrc.org/regulationgovernance/modelagreements/).

Modifications to this should be minimal, and restricted to those that are essential to make the document a full and accurate agreement about the work to be conducted.

Occasionally contracts that are not based on the National Model as described above may be considered. These cases are expected to be rare and the R&D Unit may determine that the offered draft differs sufficiently from the National Model to require detailed legal review. The R&D Unit will require an undertaking from the Sponsor to pay the costs of such a review and an initial report (the initial report) by the Trust's Legal Services Department or external solicitor. It will then refer the contract, with any national legal review that may be offered by the NIHR Clinical Research Network, to the Trust's Legal Services Department which may, at its option, refer it to external solicitors acting for the Trust. The initial report, specifying contract modifications required to protect the position of the Trust, will be sent to the R&D Unit who will forward it to the Sponsor's representative. If the Sponsor's representative is willing to accept in their entirety the contract modifications required in the initial report, the contract will be concluded on that basis. If it is not willing to accept such modifications, then either:

- Negotiations will terminate and the trial will not proceed in the Trust; or
- The Sponsor will give an unlimited undertaking to meet the Trust's legal costs and negotiations will proceed directly between the Sponsor's representative and an external solicitor instructed to act for the Trust.

The R&D Unit's decision will be final on whether or not the Sponsor's representative's acceptance of contract changes required in the initial report constitutes acceptance 'in their entirety'.

7 Related SOPs and Documents

R&D/S02	Application to the Trust for Sponsorship of a CTIMP
R&D/S08	Monitoring of Trust Sponsored Research Studies
R&D/S09	Set up and Management of Research Studies
R&D/S14	Granting NHS Permission
CRF/T07	York Clinical Research Facility Memorandum of Understanding
R&D/T10	Research Contract Signature Memorandum
R&D/T11	Co-Sponsorship Agreement Template
R&D/T12	Sub-Contract Template
R&D/T17	nMCTA Responsibility Schedule – Trust modifications