**York and Scarborough Teaching Hospitals NHS 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/or Q-Pulse 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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: https://www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse



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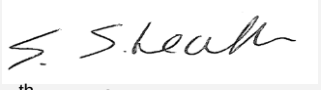
| | Signature: |  |
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This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise

## 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. |
| 4.0 | 4th November 2019 | Change of author. Removal of references to York Clinical Research Facility. Update and clarification on R&D processes. Change of link to R&D website. |
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# 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
- 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

Where the Trust is the Sponsor or Co-Sponsor of the CTIMP, the R&D Unit will represent the Trust in relation to all contracts required in connection with the study. This will be overseen by the Trial Management team

Where the Trust is Hosting an externally Sponsored CTIMP the contract should never be negotiated or signed without the review and authorisation of the R&D Unit. In such cases the contract should be sent to the studies assigned Research Delivery Facilitator.

Within the R&D Unit the Head of R&D 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 Contracts and Sponsorship Manager has primary responsibility for CTIMP contract management.

### 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 and Scarborough Teaching Hospitals 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 will vary dependant on the overall all financial value of the contract; please refer to Appendix 8.1.

The R&D Unit will send CTIMP contracts to the appropriate signatory. 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 Research Delivery Facilitator 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 Contracts and Sponsorship 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.

# 5 Contract planning and drafting for Trust Sponsored or Co-Sponsored CTIMPs

## 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 and Scarborough Teaching Hospitals 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 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 Contracts and Sponsorship 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.

Where the study involves the allocation or necessary protection of Trust-owned Intellectual Property rights, necessary agreements or clauses may also need to be reviewed by the R&D Units IP Reviewer, who in turn may need to refer the agreement to the Yorkshire & Humber NHS innovation hub and IP experts, Medipex in order to ensure legal protections. Please refer to the related SOP in section 7.

### 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 (please refer to Appendix 8.2) 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

### 6.1 Responsibilities and Review Process

Where the Trust is hosting a CTIMP sponsored by an external organisation the contract should be assigned the clinical directorate's associated Research Delivery Facilitator (RDF)

The template contract offered by the Sponsor will be reviewed and negotiated by the assigned RDF in accordance with the Trust's Confirmation of Capacity & Capability review process; please refer to the related SOP 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.

On completion of their review, and once all negotiations and necessary amendments are complete the RDF or supporting R&D Admin Coordinator will liaise with Sponsor and Trust authorised signatory to finalise the agreement.

A copy of the finalised agreement should be filing with the CTIMP Contract file which is securely located within the R&D Unit whilst an additional copy should be provided to the Research Team for filing in the Investigational Site File (ISF). An electronic scanned copy of the agreement will also be kept on the R&D shared drive and on the project sites EDGE files.

### 6.2 National Model Agreements

The Trusts preference is for Sponsors to utilize the UK-wide model Non-Commercial Agreement (mNCA) or Commercial Model Clinical Trial Agreements (mCTA)**;** please refer to Appendix 8.2 and 8.3.

Modifications to these 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.

Should the Sponsor provide a contract not based on the National Model as described above, such contracts will still be considered and reviewed by the RDF. However the Sponsor should expect that in such cases the review time for such agreements may be longer than that required for National Model Agreements as additional legal advice may be need to be consulted

### 6.3 Contractual Conflicts and Legal Advice

In the event of complications or unacceptable wording, particularly with regards the use of non-Model agreements, the RDF may be required to discuss the issue with the Head of R&D who may determine that it is necessary for it to be escalated to expert legal services for further review.

The R&D Unit have agreements in place with the Trust solicitors who can provide advice and review of such contracts at a service cost to the department.

On review by Trust solicitors communication via email 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

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|---|---|
| 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 | Issuing Confirmation of Capacity and Capability |
| R&D/S93 | Intellectual Property |
| R&D/T11 | Co-Sponsorship Agreement Template |
| R&D/T12 | Sub-Contract Template |
| R&D/T17 | mNCA Responsibility Schedule – Trust modifications |

# 8 Appendixes

## 8.1 YTHFT Authorised Signatories for Clinical Research Contracts

The below table outlines the internal agreement for Trust authorised signatories for clinical research contracts dependant on the total contract value;

| | | Authorised Signatory | Contract Value |
|---|---|---|---|
| **Research and development** | Approval of Trust research and development contracts to be supported by a business case including workforce implications (including variations or extensions):<br>NB: All Generic Research Team activity to be signed off by Deputy CE or Finance Director or Chief Executive | Head of Research & Development | Up to £200K |
| | | Deputy CE or Finance Director or Chief Executive | £200K - £500K |
| | | Executive Board | £500k - £1m |
| | | Board of Directors | Over £1m |

'Contract Value' is defined as the full potential sum of all contracted income being provided to the Trust by the other Party(ies).

## 8.2 UK-wide model Non-Commercial Agreement (mNCA)

The current template version of the UK-wide model Non-Commercial Agreement (mNCA) may be downloaded via the following link to the IRAS webpage; this includes both the template and supporting guidance notes;

https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx#mNCA

## 8.3 UK-wide Commercial model Clinical Trial Agreement (mCTA)

The current template version of the UK-wide Commercial model Clinical Trial Agreement (mCTA) may be downloaded via the following link to the IRAS webpage; this includes both the template and supporting guidance notes;

https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx#mCTA-CROmCTA