STANDARD OPERATING PROCEDURE

CONTRACTS
S07

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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
V1.1	30 April 2014	Minor typographical and formatting errors corrected. Amended wording in section 5.2.

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1. BACKGROUND

This Standard Operating Procedure (SOP) establishes a procedure for putting in place suitable contracts for clinical trials of investigational medicinal products (CTIMPs) in the Royal Devon & Exeter NHS Foundation Trust (RDEFT) to support compliance with the UK Clinical Trial Regulations and Trust governance.

2. PURPOSE

This SOP describes the processes for preparing, negotiating and executing legally binding contracts between the RDEFT and one or more third parties which relate to the funding (or other support), governance, management, conduct, or apportionment of liability for research studies sponsored/co-sponsored by or taking place at RDEFT.

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

3. SCOPE

This SOP will apply to the Research & Development (R&D) Department, other Trust Department's involved in Research and Development and to Investigators conducting research studies sponsored by the Trust (solely or jointly with the University) or participating in studies sponsored by other organisations.

4. RESPONSIBILITIES

This SOP is aimed at:

- R&D Department personnel who are responsible for preparing, reviewing, negotiating and approving contracts relating to the conduct of CTIMPs, whether these are:
    1. sponsored or co-sponsored by the Royal Devon & Exeter (RD&E); or
    2. sponsored by external organisations and hosted by the RD&E;
- Authorised research contract signatories in the Trust.

In explaining the process followed in the Trust it also contains information that will be useful for external organisations wishing to enter into CTIMP-related contracts with RDEFT.

5. PROCEDURES

5.1 Responsibilities of the R&D Department

All contracts required in connection with the Trust sponsorship, co-sponsorship or hosting of a CTIMP must be managed by the R&D Department. This is essential to ensure the Trust complies with the UK Clinical Trial Regulations, other applicable law, its own organisational governance arrangements, RD&E RD Committee requirements and all relevant Trust SOPs.

CTIMP contracts should never be negotiated or signed by members of the Trust without the involvement of the R&D Department. Within the R&D Department the RM&G Manager has primary responsibility for contract management. The Directorate Manager of R&D may take responsibility for management of specific contracts. The RM&G Manager and Directorate Manager of R&D may deputise for each other in relation to activities under this SOP.

5.2 Signature of CTIMP contracts

In order to ensure compliance with internal governance arrangements, the Trust has identified research contract signatories. For Commercial Contracts, this will be the Medical Director(s), for all other research contracts, the signatories will be either the Directorate Manager of R&D or the RM&G Manager, if delegated.

The R&D Department will send Commercial contracts to the appropriate signatory with a covering memorandum from the relevant contact.

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

6. Contracts relating to CTIMPs sponsored by RD&E Foundation Trust

6.1 Identification of contracting parties

As soon as the proposed trial has passed its 'feasibility review' by the R&D Local Research Committee (see R&D/CTIMP Sponsorship/S09) the CI should arrange a meeting with the Directorate Manager of R&D to discuss contract requirements. All required contracts should be identified at this point. This should include any organisation or individual consultant outside the Trust that will be involved in the trial in any way. The following list of possible contracting parties is illustrative and not exclusive:

- A Co-Sponsor – an organisation such as a university, that is going to share the responsibilities of CTIMP sponsor with the Trust;
- 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.

6.2 Dealing with contracting parties

The R&D Department will establish communication with appropriate representatives of contracting parties and conduct contract negotiations. In doing so, the R&D Department will consult involved members of the sponsoring Trust's staff as appropriate – including the Chief Investigator, Finance Managers and representatives of key support departments such as Pharmacy, Laboratories, or Radiology.

Where contracted services are to be provided by external organisations, for example IMP supply or laboratory tests, the R&D Department will obtain from them appropriate evidence of competence to carry out the services. This may take the form of accreditation or inspection evidence or other suitable evidence as the R&D Department may determine. If necessary the R&D Department will seek advice from senior staff in relevant departments of the sponsoring Trust.

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 Trust; the R&D Department will liaise with appropriate members of the sponsoring Trust's staff to ensure that these arrangements are correctly made.

6.3 Contract drafting for RD&E Foundation Trust sponsored studies

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 Department, these are clear, cover all relevant matters and place no unduly onerous obligations on the RD&E Foundation Trust.

For contracts between the Trust and other NHS Trusts that will be trial sites or for contracts between:

(1) The Trust and another party as co-sponsor and
(2) other NHS Trusts that will be 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.

In the event that a particular trial has very unusual contracting requirements the R&D Department may seek the advice of the Trust's Legal Services Department.

6.4 Contracts relating to CTIMPs sponsored by external organisations

Section 4 above applies in its entirety to 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 Department as part of the NHS Permission application, in accordance with R&D/NHS Permission for CTIMPs/S21.

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 in the Trust, 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.

Very exceptionally, contracts that are not based on the National Model as described above may be considered. These cases are expected to be rare and are restricted to situations where the Sponsor is a non-UK organisation. In such circumstances, the R&D Department will require an undertaking from the Sponsor to pay the costs of 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 Department 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 Department'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. FURTHER READING

R&D/CTIMP Sponsorship/S09
R&D/NHS Permission for CTIMPs/S21

APPENDIX 1 – DEFINITIONS

APPENDIX 2 – ABBREVIATIONS