### Title of Standard Operating Procedure:

RDSOP13 Contracts Management

### Document Summary:

To describe the processes for contracts/agreements to be put in place by the Research Office on behalf of the Trust, between the Trust and the sponsoring organisation and/or their delegate.

### Document Author:

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### Target Audience:

Trust-wide, Research Community, Internal and External Researchers

### Consultation:

R&I Office, research community and R&I Committee members

### Approval Committee:

R&I Committee

### Cross Reference Document(s):

Research Approval Policy
All Trust R&I SOPs

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### Minimum Monitoring Requirement

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Frequency</th>
<th>Process for Monitoring</th>
<th>Evidence</th>
<th>Responsible Individual(s)</th>
<th>Response Committee(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review of SOP content</td>
<td>Annually</td>
<td>Review by Author, redraft, submission to R&amp;I Operational Group</td>
<td>Minutes of R&amp;I Operational Group</td>
<td>Head of R&amp;I Office</td>
<td>Research &amp; Innovation Committee</td>
</tr>
</tbody>
</table>
## Contents

1. Introduction................................................................................................................. 3  
2. Purpose ....................................................................................................................... 3  
3. Roles and Responsibilities .......................................................................................... 3  
3.1 Duties within the Organisation .............................................................................. 3  
4. Procedure .................................................................................................................... 4  
4.1 Template contracts .................................................................................................. 5  
4.2 Review of Contracts ................................................................................................. 5  
4.3 Contract Approval .................................................................................................... 6  
4.4 Sub contracts ............................................................................................................ 6  
4.5 Commercially funded investigator led studies ....................................................... 7  
4.6 Commercial Disclosure Agreements ................................................................. 7  
5. References .................................................................................................................. 8  

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Operating Procedure

1. Introduction

All commercially sponsored research projects must have an appropriate contract between the Trust and the sponsoring organisation and/or their delegate (e.g. Clinical Research Organisation) who will be managing the project. Non-commercially sponsored studies may require an agreement/contract to be in place with the Trust to ensure that the financial and governance aspects of the trial are managed effectively between the Trust and the University. Other agreements may be submitted to the Trust for signature e.g. funding agreements, confidentiality disclosure agreements, and material transfer agreements. Contracts/agreements supplied by sponsoring/funding organisations are reviewed by the Research Office and signed on behalf of the Trust by the Trust authorised signatory. Researchers must be aware that they cannot begin their research study until a contract/agreement has been completed between the Trust and the sponsoring/funding organisation.

2. Purpose

To describe the processes for contracts/agreements to be put in place by the Research Office on behalf of the Trust, between the Trust and the sponsoring organisation and/or their delegate.

3. Roles and Responsibilities

3.1 Duties within the Organisation

It is the responsibility of the Research & Innovation Office to make Trust R&I SOPs available to all research active staff working on Trust-approved research studies.

It is the responsibility of the study Chief Investigator (CI) or local Principal Investigator (PI) to ensure that up-to-date copies of Trust R&I SOPs are available to research staff.

It is the responsibility of the study Chief Investigator or local Principal Investigator to ensure up-to-date SOPs are filed in the Investigator Site File and are available to research staff, and to inform the Research Support Co-ordinator of the names of all research staff involved on a study so that copies of SOPs can be distributed appropriately.

It is the responsibility of the study Chief Investigator or Principal Investigator to designate if the SOPs of another organisation are to be followed for a study. For example those of a Clinical Research Network or commercial sponsor. If there is significant conflict between the external SOP and the Trust R&I SOP it is the
responsibility of the CI or PI to resolve these with the Research Office prior to starting the study.

It is the personal responsibility of all staff to follow Trust (or the designated alternative organisations) procedural documents.

The Research & Innovation Office is responsible for managing Trust R&I SOPs including their approval, dissemination and archiving. All Trust R&I SOPs must be published on the Trust website.

4. Procedure

4.1 Template Contracts

National template Agreements/Contracts have been created for the following scenarios and the Trust has fully adopted the use of these template Agreements. The Research Office will propose the use of the appropriate template if an appropriate agreement has not been proposed by the Sponsor. Up-to-date versions of these templates can be found on:


Commercial Model Clinical Trial Agreements (mCTA and CRO-mCTA) The February 2018 revised model Clinical Trial Agreement (mCTA) and Clinical Research Organisation model Clinical Trial Agreement (CRO-mCTA) templates are designed to be used without modification for industry-sponsored trials in NHS/HSC patients in hospitals throughout the UK Health Service

Non-Commercial Sponsored studies. The model Non Commercial Sponsor Agreement (mNCA) will be used with appropriate modifications negotiated between Sponsor and NHS Trust as required.

4.2 Review of Contract

For Trust sponsored studies, the Trust will propose the use of the mNCA for clinical trials and other multi-centre studies.

For non-Trust sponsored studies, the Research Office will request a contract to review from the sponsor or delegate at first contact and will recommend the use of the appropriate contract.

Any changes other than those required to identify the Sponsor, Site, or study specific details, will be referred to the R&I Manager for review.
A formal response to the changes will be emailed to the Sponsor or delegate.

The R&I office will be responsible for:

Negotiating with the company to ensure their set up fee is organised;
Negotiating with other departments (Trust and/or University) contributing to the study, so that their costs are recovered.

The Research Office will ensure the R&I Accountant authorises the study costs/funding within the Contract prior to agreement of the final version to be prepared for signature.

Once the budget has been agreed between the PI, the R&I Accountant and Sponsor then this information will be used by the Research Office to set-up a new non-charitable grant code with the R&I Accountant. The Accountant will not initiate an account without first liaising with the Research Office (i.e. the PI cannot set up an account alone).

The R&I Accountant will provide the R&I Grants Co-ordinator with an account code and this will be provided to the Sponsor to include along with banking details in the financial appendix of the contract. The PI will also be informed of the account details.

### 4.3 Contract Approval

Once the detail of the contract has been agreed a final contract will be requested in triplicate to be forwarded to the Research Office for signature. The final version will be checked by the R&I Manager and compared with the final agreed version prior to forwarding for signature. If all other items are in place as per RISOP4 Research Approval Process (including amendments) then the project file will be prepared by the R&I Officer and forwarded for signature by the authorised signatory as per the Authorised Signatory List and both the Contract and approvals paperwork signed on behalf of the Trust.

A copy of the contract will be retained by the Research Office, a copy will be sent to the PI for filing in the site file, and the last copy returned to the Sponsor (along with the final approval documentation).

### 4.4 Subcontracts

For studies led by a University employee, the main contract is negotiated and signed as above. However, a subcontract between the Trust and University is initiated so that appropriately apportioned study funds are managed through the University and not the Trust. The details of the subcontract will have been prepared by the R&I Accountant in negotiation/liaison with the University Research Business Manager and the financial details forwarded to the Research Office to prepare the subcontract ahead of Research Approval.
The R&I Grants Co-ordinator liaises with the Contracts Department of the Faculty of Health Sciences and sends an agreed template subcontract for their review/authorisation prior to Research Approval. Amendments will be negotiated and finalised ahead of Research Approval. The University will sign two copies of the subcontract and send these to the R&I Grants Co-ordinator. This prior agreement of the subcontract by email will ensure that the Trust is able to approve the study and issue the subcontract to the University simultaneously enabling the PI to recruit as soon as able following Trust approval.

A copy of the main contract between the Trust and Sponsor and also the Trust R&I approval will be forwarded with the subcontract to the University.

Research Staff with honorary clinical appointments are covered as Agents of the Trust under the terms of the Form of Indemnity in the appendix of model agreements therefore a separate form of indemnity between Sponsor and University is not required.

4.5 Commercially funded investigator led studies

Where there is commercial funding, but the company is not acting as sponsor (usually the Trust will act as sponsor or co-sponsor, see RISOP14 Sponsorship), then a similar process is followed. Often there will be no standard agreement and the negotiation may be more ad hoc and tailored to the situation. Key areas of negotiation in these situations will involve clarifying the intellectual property arrangements for the project and ensuring this is clearly defined, that patient confidentiality is maintained, and indemnity arrangements. Any negotiation is conducted by the R&I Director (or R&I Manager if unavailable) and appropriate clauses extracted and used as required from model Agreements.

4.6 Confidentiality Disclosure Agreements (CDA’s)

CDA’s are often also referred to as Non-Disclosure Agreements/Secrecy Agreements. These agreements are usually forwarded by companies for signature when they wish to share their protocols with Trust researchers to enable the researcher to decide if they wish to become involved in the study.

The company would wish to protect their Intellectual Property (IP) rights under cover of these legal documents.

These agreements must be reviewed by the Research Office. The Research Office will liaise with a TrusTech representative for advice as appropriate and negotiate any changes required. The agreement must be signed by the Trust authorised signatory as per any other Research Agreement (refer to the Trust policy for Intellectual Property Management). Researchers must not sign these agreements themselves as in so doing they would potentially be accepting liability for any breaches by themselves and colleagues without insurance.
5. References