UNIVERSITY OF LEICESTER, LOUGHBOROUGH UNIVERSITY
&
UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

JOINT RESEARCH SUPPORT OFFICE

STANDARD OPERATING PROCEDURES

UHL Research Support Office
SOP S-1005 UHL V6 August 2018

Standard Operating Procedure for Management of Contracts for research sponsored by University Hospitals of Leicester NHS Trust (UHL)

PGC Reference: C4/2014

OFFICE BASE

Research & Innovation
Leicester General Hospital
Gwendolen Road
Leicester
LE5 4PW
1 Introduction

This Standard Operating Procedure (SOP) describes the procedures used by the University Hospitals of Leicester NHS Trust (UHL) when providing and managing agreements with Third Parties, where the UHL is the Sponsor of research.

The outcome is that the UHL is able to manage the ongoing contractual process throughout the duration of a research Study.

It is essential that clear agreements describing allocation of roles and responsibilities are reached and documented prior to any Study-related procedure commencing.

2 Scope

This SOP applies to all staff, and any external individual who approach the UHL to request that the organisation act as Sponsor for research activity.

3 Procedure

It is expected that during the UHL Sponsor Green Light and Risk Assessment process, Third Parties and NHS sites will be identified in order for appropriate agreement negotiations to begin. It is a requirement that before services commence a written agreement between the UHL and the Third Party be fully executed. Where it is necessary for a Third party to commence pre-trial set up activity, a letter of intent will be provided to allow these activities to begin.

The Head of Research Operations or their delegate will forward details of the study to the R&I Contracts Team appropriate action.

Third Party Agreements may include, but are not limited to those between:

a. The UHL and Participating Organisation(s) – Research sites.

b. The UHL and another Co-Sponsor or Joint Sponsor.

c. The UHL and Funder(s).

d. The UHL and Organisations providing a service (e.g. statistical support, CRO, Monitoring; CTU etc).

e. The UHL and providers of medicinal products or equipment

f. The UHL and any collaborators not covered above

Third Party Agreements include contracts, clinical trial agreements, service level agreements, roles and responsibilities documents, forms of work or similar documents.

The form of the Third party agreement should be proportionate to the level of risk associated with the Study and the type / nature of the other organisation(s) involved. It is expected that the UHL will use nationally approved standard templates where applicable and appropriate.

The contracts process is managed through the EDGE system as appropriate and the relevant Attributes and Workflows completed.

The Contract and Review process is attached at Appendix 1.
3.1 Third Party / Vendor Agreements

Third Party Agreements are used to document and agree aspects of the relationship between the UHL and the Third Party organisation(s), including, but not limited to:

a. Roles and Responsibilities.
b. Financial and legal considerations including indemnity.
c. Termination considerations.
d. Standards of service.
e. Regulatory obligations including Data Protection.
f. Intellectual property & publication considerations.
g. Confidentiality considerations.

The Contracts Team will generate and manage the contract process to full execution. Contracts will be submitted for signature. The Director of R&I, Assistant Director of R&I and the Head of Research Operations are the authorised signatories on behalf of the UHL for all Research related contracts.

Once fully signed, ONE (1) will be kept by UHL Sponsor, ONE (1) to be kept by the Third Party and ONE (1) to be placed in the Trial Master file.

In cases of Multi-Centre studies, it is recommended that a copy be kept in the Investigator Site File at each site. A copy must be retained by UHL Sponsor within the EDGE instance for each site (RED LEVEL).

This SOP does not cover employment or Human Resources related contracts.

4 Responsibilities

<table>
<thead>
<tr>
<th>Responsibility</th>
<th>Undertaken by</th>
<th>Activity</th>
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<tbody>
<tr>
<td>1 UHL Sponsor</td>
<td>Contracts Team</td>
<td>Confirm the necessity for Third Party Agreements during the Sponsor Risk Assessment and Green Light Process</td>
</tr>
<tr>
<td>2 UHL Sponsor</td>
<td>Contracts Team</td>
<td>Ensure that all Third Party agreements are drafted, reviewed, negotiated and approved, ensuring that responsibilities of all parties are accurately documented.</td>
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<tr>
<td>3 UHL Sponsor</td>
<td>Contracts Team</td>
<td>To ensure that all relevant departmental staff involved in the study, and UHL support staff are adequately consulted during negotiations and prior to the contract execution.</td>
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<tr>
<td>4 UHL Sponsor</td>
<td>Head of Research Operations / Contracts Team</td>
<td>Ensure Third Party Agreements are appropriately filed</td>
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5 Monitoring and Audit Criteria

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<tr>
<th>Key Performance Indicator</th>
<th>Method of Assessment</th>
<th>Frequency</th>
<th>Lead</th>
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All research sponsored by UHL has appropriate contracts in place. | Included in the monitoring / audit programme. | Random audits / monitoring conducted on a risk based approached according to research activity. | Head of Research Operations

This table is used to track the development and approval of the document and any changes made on revised / reviewed versions

### DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT

<table>
<thead>
<tr>
<th>Author / Lead Officer:</th>
<th>Carolyn Maloney</th>
<th>Job Title: Head of Research Operations</th>
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<tbody>
<tr>
<td>Reviewed by:</td>
<td>Research &amp; Innovation Management Meeting</td>
<td></td>
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<tr>
<td>Approved by:</td>
<td>Prof. Nigel Brunskill</td>
<td>Date Approved: 17 DEC 2013</td>
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### REVIEW RECORD

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<th>Reviewed By</th>
<th>Description Of Changes (If Any)</th>
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<tr>
<td>13/01/2014</td>
<td>2</td>
<td>R&amp;D Management Meeting</td>
<td>Alignment to University process.</td>
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<tr>
<td>21/04/2015</td>
<td>3</td>
<td>R&amp;I Management Meeting</td>
<td>Change of Logo &amp; Office name</td>
</tr>
<tr>
<td>02/08/2016</td>
<td>4</td>
<td>CM, DW</td>
<td>Consistency check and addition of Appendices</td>
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<tr>
<td>13/02/2017</td>
<td>5</td>
<td>CM</td>
<td>Change of Logo</td>
</tr>
<tr>
<td>May, Sep 2018</td>
<td>6</td>
<td>CM, RP, DW, LW CCL</td>
<td>May 2018: Amend process to reflect use of EDGE and processing of contracts. Sep 2018: Updated logo</td>
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### DISTRIBUTION RECORD:

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CONTRACT REVIEW & APPROVAL PROCESS – UHL SPONSORED STUDIES

When is a contract required?

There will be some form of contract or agreement required for all research studies sponsored by UHL. The types of contract/s vary depending on the type of study.

UHL R&I department will draw up all contracts where UHL is the Sponsor.

Types of Contracts/Agreements

All Chief Investigators must sign the Roles and Responsibilities of Chief Investigator document.

This will be requested as part of the Sponsor Review Process.

Most common types of contracts generally drawn up and agreed are:

- Model Agreements for Clinical Trial studies – mCTA
- Model Agreement for Non Commercial Research - mNCA
- Model Agreement for Clinical investigation with Medical technology – mCIA
- Model Agreement for Tripartite Clinical Trial studies – CRO mCTA
- Material transfer Agreement - MTA
- Collaboration Agreements with Universities
- Site Services Agreement
- Service Level Agreement
- Statement of Activity (New HRA Process)
- Miscellaneous agreements such as non-disclosure confidentiality agreement, consultancy, sample testing, interviews etc.
UHL Sponsor or the Chief Investigator informs the Contracts team of the study taking place at UHL. A copy of the grant application and draft contract including costings must be sent to the Contracts team. Details of costs/supplies will be provided to the participating sites if applicable.

Contracts team to agree and sign off the grant related contract

Appropriate contract templates & statement of activities will be drafted by the Contracts team and then to be sent to the HRA by either the CI or study project manager

Once contracts have been approved by the HRA or grant organisation the Contracts team commences the signature process or sends the draft contracts to the participating sites