Standard Operating Procedure R&D/SOP005

Management of Contracts for Research Projects

1. Scope

This SOP will apply to the R&D Department, the Cambridge Clinical Trials Unit, other Trust Departments 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.

2. Purpose

This SOP describes the processes for preparing, negotiating and executing legal binding agreements ("Agreements") between Cambridge University Hospitals NHS Foundation Trust ("the Trust") and one or more third parties which relate to the funding (or other support), governance, management, conduct and apportionment of liability for research studies sponsored by or taking place at Cambridge University Hospitals NHS Foundation Trust.

The following are outside the scope of this SOP:
- Supplies of reagents
- Imaging agents
- Challenge agents (as defined in Chapter 3 of Volume 10 of the publications "The rules governing medicinal products in the European Union")
- Equipment which is not the subject of the Clinical Trials Authorisation or of the study

3. Definitions and Abbreviations

The headings below contain the definitions of terms and meaning of abbreviations used within the document.

Common abbreviations and definitions can be found in CCTU/INF001 Common Abbreviations and Definitions.

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Trust-Sponsored</td>
<td>Sponsored by Cambridge University Hospitals NHS Foundation Trust (CUH) or sponsored by CUH jointly with The University of Cambridge or jointly with other organisations</td>
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3.1. Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Meaning</th>
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<tr>
<td>IPR</td>
<td>Intellectual Property Rights</td>
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<tr>
<td>R&amp;D</td>
<td>Research and Development</td>
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4. **Undertaken by**

R&D staff all have specific responsibilities in the process, they are:

**Solicitor Consultants (Legal Team)** are responsible for reviewing, preparing, negotiating and approving all agreements, liaising with relevant staff and support departments in order to finalise agreements.

In the absence of the Legal Team (annual or sick leave), all enquiries regarding issues of liabilities, indemnities or insurance should be addressed to the Assistant Director, Medico-Legal and Patient Experience Team.

**Cambridge Research Office contracts team** prepare and/or negotiate agreements for research involving University staff, in collaboration with the Legal Team.

**Cambridge Clinical Trials Unit** identify when an agreement may be required and notifying the Legal Team. They may agree amounts of funding or drug to be supplied under the agreement.

**R&D Manager** is the authorised signatory for all research agreements within specified limits, or in his absence the Solicitor Consultant may sign research agreements which they have not negotiated.

**Study Team** will send draft agreements to the Legal Team or Commercial Trials Manager for review.

**R&D Research Governance Coordinator/Assistant** RGCs and RGAs identify when an agreement is required and notify the Legal Team. RGCs and RCAs negotiate confidentiality agreements and template non-commercial agreements, liaising with the Legal Team where the terms differ from the CUH standard terms. RGCs and RCAs are responsible for reviewing, preparing, negotiating and approving financial details of commercial trial agreements and their terms, liaising with relevant staff and support departments in order to finalise agreements.

5. **Items Required**

R&D/SOP001 Delegation of Roles and Responsibilities
CCTU/SOP047 CTIMP Start Up Procedure for Trial Teams
CCTU/SOP048 CTIMP Start Up Procedure for Regulatory Team

6. **Summary of Significant Changes**

Change in roles RGCs and RGAs
7. **Method**

The following sections provide a description of the processes to be followed when implementing this document’s procedures.

7.1. **Studies Submitted through R&D**

- Where a study or a substantial amendment is submitted for R&D approval the RGCS, RGAs, Clinical Trials Officers or Clinical Trials Monitors with guidance from the Legal Team where appropriate will identify contractual issues including, but not limited to:
  - Funding
  - Sponsorship
  - Supply of drug/placebo/medical devices
  - Supply of tissue/organs
  - Supply of data
  - Provision of services for example scans, biochemical analyses or genetic analyses
  - Patient recruitment/participating sites
  - Statistics/Pharmacovigilence
- All necessary agreements relating to the above must be in place before Trust approval is granted
- The Legal Team will also review, negotiate (where applicable) and arrange signature for any additional agreements which arise in the course of the study and which do not require a substantial amendment

7.2. **Agreements sent directly to the Study Team**

Draft agreements relating to studies, which are sent directly to the study team will be forwarded to the Legal Team or if applicable to the Cambridge Research Office for review.

7.3. **EU Trials of an Investigational Medicinal Product**

For studies that fall under the EU Directive and the Medicines for Human Use (Clinical Trials) Regulations, the Trial Master Files may be reviewed on a case-by-case basis by the Legal Team to ensure that all necessary agreements are in place.

7.4. **Review of Agreements**

Where applicable, agreements will be based on the appropriate NIHR templates for commercial research, non-commercial research and collaborative research in the NHS found on the NIHR website. However, other starting points for agreement(s) are acceptable at the Legal team’s sole discretion.

Agreements will include terms relating to the list below where applicable but not limited to:
- Patient safety
- Sponsorship
- Liability, insurance and indemnity
7.5.  Completion of Agreements

- Once agreements have been approved by the Legal Team one copy of the agreement for each party should be printed
- Following confirmation by the Legal Team the authorised signatory process for the Trust will be arranged by the R&D Department
- A copy of the title page of all agreements sent for signature will be placed in the folder “agreements for signature” which is held in the R&D Department until the signature process is complete
- Where Cambridge University Hospitals (CUH) is the sponsor, Participating Site Agreements and Material Transfer Agreements should in most cases be signed initially by CUH
- The date on the front page of the agreement should be left blank until the agreement has been signed by all of the parties
- The date the agreement is signed by the last party should be written by hand on all the copies of the agreement
- It is acceptable to sign a PDF copy of an agreement, and to make an agreement in counterparts

7.6.  Distribution and Storage of Agreements

- One copy of the fully executed agreement will be sent to each party of the agreement
- For agreements relating to specific studies the original wet ink (or PDF) Trust copy will be kept and stored by the study team
- Copies will be held in the R&D Department where required by the Legal Team
- For sponsored Clinical Trials of Investigational Medicinal Products (CTIMPs) a copy will be filed in the R&D Department
- All general agreements, including agreements relating to:
  - Department of Health funding
  - master agreements with third parties
  - services agreements
  - confidentiality agreements
  - assignments or licences of Intellectual Property rights

Will be held in a secure fireproof cabinet under the control of the Solicitor Consultant
8. Monitoring Compliance with and the Effectiveness of this Document

a. Process for Monitoring compliance and Effectiveness
As part of routine monitoring visits, audit and inspection

b. Standards/Key Performance Indicators
This process forms part of a quality management system. Documents are reviewed every two years

9. References
The Institute of Clinical Research, 2008, Abbreviations used in Clinical Trials.

10. Associated Documents
None

11. Equality and Diversity Statement
This document complies with the Cambridge University Hospitals NHS Foundation Trust service equality and diversity statement.

12. Disclaimer
It is the user’s responsibility to check against the electronic library that this printed out copy is the most recent issue of this document.

<table>
<thead>
<tr>
<th>Review date</th>
<th>2 years (or earlier in light of new evidence) from approval date</th>
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<tbody>
<tr>
<td>Owning department:</td>
<td>CCTU QA on behalf of R&amp;D</td>
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<tr>
<td>Supersedes:</td>
<td>R&amp;D/SOP005 V4</td>
</tr>
<tr>
<td>Local reference:</td>
<td>R&amp;D/SOP005 V5</td>
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