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

JOINT RESEARCH SUPPORT OFFICE

STANDARD OPERATING PROCEDURES

UHL Research Support Office
SOP S-1010 UHL V10 August 2018

Standard Operating Procedure for Chief Investigator Responsibilities
for research sponsored by
University Hospitals of Leicester NHS Trust (UHL)

PGC Registration - C22/2013

OFFICE BASE

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

This Standard Operating Procedure (SOP) describes the role and responsibilities of the Chief Investigator (CI) for research sponsored by the University Hospitals of Leicester NHS Trust (UHL).

The outcome is that the Chief Investigator (CI) is aware of, and has agreed to all roles and responsibilities as delegated to them by the Sponsor prior to the commencement of the research.

An individual designated as the CI for any research undertaken in or through the NHS or social services or using participants' organs, tissue or data must have appropriate experience and qualification. The CI is the person designated to take overall responsibility within the team of researchers for the design, conduct and reporting of the study.

The CI must ensure that the study is planned, set-up, conducted, documented and reported according to the protocol, relevant SOPs, International Conference on Harmonisation Good Clinical Practice (ICH-GCP) and appropriate regulatory requirements.

In the case of a single site study, a CI may also be the Principal Investigator (PI). In these cases, the roles & responsibilities of the CI will over ride those of a PI.

2. Scope

This SOP applies to ALL Chief Investigators of studies sponsored by the UHL.

3. Procedure

The CI must be an individual, with appropriate experience, expertise and training to undertake the design; conduct and analyses of the study to the standards set out in relevant legislation. They must also lead and manage others who have been delegated responsibilities in the research.

The CI has overall responsibility for the conduct of the research and is accountable to their employer, the Sponsor if different, and the host organisation where the research takes place. If the research is taking place at more than one site, the Chief Investigator takes on personal responsibility for the design, management and reporting of the study, and coordinating the personnel at the other sites.

The CI is responsible for ensuring that:

- The research team gives priority at all times to the dignity, rights, safety and wellbeing of the participants.
- The research team understand the legal and ethical requirements in research, and are familiar with the appropriate standard operating procedures and policies relating to research.
• The study complies with all legal and ethical requirements.
• The research is conducted to the standards and follows relevant frameworks as set out within the UK.
• The Trial Master File is maintained and kept inspection ready at all times.
• Each member of the research team, including those at collaborating sites, is qualified by education, training and experience to discharge their role in the study, and their qualifications are documented and retained in the Investigator Site File.
• All researchers involved in a clinical trial of Investigational Medicinal Products are aware of their legal duties.
• Students and new researchers have adequate supervision, support and training.
• A suitable sponsor is secured and agreements are in place detailing the responsibilities of all parties involved in the research.
• Trust (R&I) authorisation is obtained from each care organisation and subsequent Sponsor Green Light received prior to commencing the study at each care centre.
• The protocol is submitted for sponsor review and agreement prior to submitting for ethics / HRA review.
• The study does not start without a favourable opinion from a Research Ethics Committee, HRA approval, Trust (R&I) authorisation and where relevant competent authority (MHRA) approval and Sponsor Green Light approval.
• The research team acts on any conditions attached to the ethics opinion.
• Unless urgent safety measures are necessary, the research follows the protocol or proposal agreed by the relevant ethics committee, HRA, Trust R&I Office and by the Sponsor.
• Substantive changes to the protocol are submitted for Sponsor approval prior to ethical, regulatory and Trust authorisation before implementation, with the exception of urgent safety measures.
• Each member of the research team, who has direct involvement with participants and/or identifiable data, has an appropriate substantive or honorary contract with NHS Trust or an Honorary Research Contract or relevant letter of access via the research passport scheme.
• The CI must ensure that the clinician responsible for providing care is informed of a subject's participation in research. When the research involves a service user, or carer or a child looked after or receiving services under the auspices of the local authority, the agency director or their deputy agrees to the person being invited to participate, and is fully aware of the arrangements for dealing with any disclosures or other relevant information.
• Potential participants and other service users and carers are involved in the design and management of the study whenever appropriate.
• For clinical trials involving medicines, the research follows all conditions imposed by the licensing authority. The list of responsibilities should be documented in the Sponsorship Agreement.
• Report Serious Adverse Events to the Sponsor, R&I, Research Ethics Committee & the competent authority as required
• In accordance with relevant legislation, procedures are in place to ensure collection of high quality, accurate data and to maintain the integrity and confidentiality of data during processing and storage.
Arrangements are in place for the management of any intellectual property arising from the research. The CI should submit annual written summaries of the
study status to the Sponsor, Ethics Committee / HRA and the Competent Authority as relevant, and provide a summary outcome at the end of the study. This includes annual / end of study reports and safety reporting.

- Once established, findings from the work are disseminated promptly and fed back as appropriate to participants.
- There are appropriate arrangements to archive the data when the research has finished, and to ensure it is still accessible when required.
- All data and documentation relating to the study are available at the request of the inspection and auditing authorities.
- Where the CI delegates responsibilities to members of the research team, this must be clearly documented in a Delegation of Authority Log (template available through the R&I Webpages on the Public website). The CI remains accountable for the actions of their research team.
- Complete and sign Roles and Responsibilities document prior to commencing any part of the research study.

4. Roles and Responsibilities Document

All points listed above are included within the Roles and Responsibilities document. The CI must initial on each page, and sign at the end of the document during the Sponsor review process. Completion of this document forms part of the sponsor approval confirmation (Appendix 1).

5. Responsibilities

<table>
<thead>
<tr>
<th>Responsibility Undertaken by</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Sponsor</td>
<td>Head of Research Operations or their delegate Confirm roles and responsibilities document signed as part of the Sponsor Green light process</td>
</tr>
<tr>
<td>2 Sponsor</td>
<td>Head of Research Operations or their delegate Ensure Chief Investigator documents any delegated duties appropriately using the Delegation of Authority log.</td>
</tr>
<tr>
<td>3 Chief Investigator</td>
<td>Chief Investigator Ensures all roles and responsibilities are undertaken</td>
</tr>
<tr>
<td>4 Clinical Trials Monitor</td>
<td>UHL Monitors Ensure delegated duties are appropriately carried out and delegated appropriately</td>
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5. Legal Liability Statement

Guidelines or Procedures issued and approved by the Trust are considered to represent best practice. Staff may only exceptionally depart from any relevant Trust guidelines or

SOP S-1010 UHL Chief Investigator Responsibilities for research sponsored by University Hospitals of Leicester NHS Trust (UHL) Page 4 of 6
Version 10 August 2018

NB: Paper copies of this document may not be most recent version. The definitive version is held on the R&I Office website. http://www.leicestersresearch.nhs.uk/
Procedures and always only providing that such departure is confined to the specific needs of individual circumstances. In healthcare delivery such departure shall only be undertaken where, in the judgement of the responsible healthcare professional it is fully appropriate and justifiable – such a decision to be fully recorded in the patient’s notes and in the research site file.

6. Monitoring and Audit Criteria

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

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>R&amp;I Management Meeting</td>
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<tr>
<td>Approved by:</td>
<td>Professor Nigel Brunskill</td>
<td>Date Approved: 13/11/18</td>
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REVIEW RECORD

<table>
<thead>
<tr>
<th>Date</th>
<th>Issue Number</th>
<th>Reviewed By</th>
<th>Description Of Changes (If Any)</th>
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<tbody>
<tr>
<td>March 2015</td>
<td>3</td>
<td>R&amp;I Management Meeting</td>
<td>Updates to Logo and personnel titles.</td>
</tr>
<tr>
<td>October 2015</td>
<td>4 &amp; 5</td>
<td>Carolyn Maloney</td>
<td>Version of SOP to correlate with appendix</td>
</tr>
<tr>
<td>July 2016</td>
<td>7</td>
<td>CM, LW, JJ</td>
<td>Add in HRA and consistency check.</td>
</tr>
<tr>
<td>February 2017</td>
<td>9</td>
<td>Carolyn Maloney</td>
<td>Update to Logo</td>
</tr>
<tr>
<td>March, August 2018</td>
<td>10</td>
<td>CM, CCL</td>
<td>Revision to wording in some clauses. Nothing substantial. Updated R&amp;I logo</td>
</tr>
</tbody>
</table>

DISTRIBUTION RECORD:

| Date | Name | Dept | Received |
|------|------|------|----------|----------|
Roles & Responsibilities of Chief Investigator Agreement

<table>
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<tr>
<th>Study Title (in full):</th>
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<tr>
<td>Reference No:</td>
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The Chief Investigator (CI) and all members of the research team shall comply with all current regulations (as amended from time to time) applicable to the performance of the study including, but not limited to:

- Policy framework for Health and Social care or relevant Governance Framework.
- The Principles of the World Medical Association Declaration of Helsinki
- Data Protection Act (1998/2018)
- General Data Protection Regulations (2018)
- UK Medicines for Human Use (Clinical Trials) Regulations (2004)
- UK Medicines for Human Use (Clinical Trials) Amendment Regulations 2006, SI 2006/1928
- The UK Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006, SI 2006/2984
- The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008, SI 2008/941
- The Mental Capacity Act (2005)

I confirm that I have read and understood my responsibilities as listed above

<table>
<thead>
<tr>
<th>CI Initials:</th>
<th>Date:</th>
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<tbody>
<tr>
<td>Date</td>
<td>Initials</td>
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Above guidelines

- Confirmation that the protocol has undergone appropriate scientific and ethical review and is compliant with the relevant regulations
- All ethical permissions have been obtained
- Evidence that all support departments have agreed in writing to provide services required
- The study is adequately resourced and has been signed off by a C1 Finance Lead
- Substantiation of Honorary Contract is not held with the NHS Trust Letters of Access or Honorary Research Contracts have been obtained
- Evidence of appropriate permission to access NRS resources for each member of the research team
- Where a Monitoring Team has been received a C1 where applicable
- Monitoring arrangements have been discussed and confirmed through the C1 Monitoring
- Appropriate Ethics Committee

- Approval by Sponsor

The C1 must not permit the study to commence at any site until formal confirmation of Sponsor’s (Green Light) has been received.

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**Roles & Responsibilities of Chief Investigator Agreement**

**Green Light**

NHS Trust

University Hospitals

SHN

**Research**
Roles & Responsibilities of Chief Investigator Agreement

During the study it is the CI responsibility to ensure that:

- The study is conducted in accordance with the approved version of the protocol and subsequent amendments
- Delegation of any responsibilities are clearly documented on the Delegation of Authority Log before study activity commences, and the Sponsor kept informed of personnel changes
- All participants are consented using the correct version of the consent form as well as using the process agreed and documented in the application
- Access by UHL Sponsor representatives to all consent forms is facilitated where necessary to perform audits during the course of the study
- Reporting of Urgent Safety Measures (USM) and subsequent management in line with Regulatory requirements
- Amendments are submitted to the Sponsor prior to submission to the relevant authorities i.e. MHRA, REC/HRA. Evidence of approval must be provided to the Sponsor prior to their implementation – unless in emergency circumstances (USM), where retrospective approval is acceptable
- The Investigator Brochure (IB) or Summary of Product Characteristics (SPC) is reviewed and where appropriate updated annually and recorded in the TMF
- A Trial Master File (TMF) is created, including individual sections for additional sites where required
- All relevant Standard Operating Procedures and policies have been made available to research team and a 'read record' retained in the study team training file
- Annual progress on the anniversary of the Ethics Favourable Opinion and where relevant, Development Safety Update Reports (DSUR) on the anniversary of the Clinical Trials Authorisation are produced and sent to the Sponsor prior to submission to relevant agencies
- All communication to the MHRA, REC/HRA, and other regulatory bodies are copied to the sponsor representative for authorisation and processing where relevant
<table>
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<th>C/ Initials</th>
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I confirm that I have read and understood my responsibilities as listed above.

- Act as the Data Controller as delegated by the sponsor on a study by study basis.
- The Reference Sapphire Information (RSI) is updated as appropriate.
- The Reference Safety Information Plan is in place prior to database lock if applicable.
- Study is registered as appropriate on a relevant protocol registration scheme e.g. Clinicaltrials.gov.
- The Statistical Analysis Plan is in place.
- Quality control systems for the validation of data when using self-built software programmes rather than pre-packed software are in place.
- Study is locked and secure.

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References No:

Study Title (in full):

Roles & Responsibilities of Chief Investigator Agreement

University Hospitals SHN
# Roles & Responsibilities of Chief Investigator Agreement

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### At the end of the study, the CI must ensure that:

- End of study notification is completed and sent to the Sponsor for review and processing
- Documents relating to the study are archived in accordance with the Archiving SOP
- The Sponsor is notified of any outputs, publications or changes in service as a result of the study

I confirm that I have read and understood my responsibilities as listed above  
CI Initials:  
Date:  

### For Multi-site studies ONLY. It is the Chief Investigator responsibility to ensure that:

- The Sponsor is consulted **BEFORE** applications to expand the study into additional sites is made
- All documentation relating to the application to additional sites is copied to the Sponsor
- Feasibility is received from each participating site
- Ensure that no recruitment related activity commences at any site prior to the Sponsor Green Light confirmation being received for that site
- All research staff at additional sites are appropriately trained in ICH GCP and consent in accordance with Sponsor requirements
- All members of the Site Study Team are able by knowledge, training and experience to undertake the roles they accept
- An Investigator Site File containing the essential documents is maintained and inspection ready at each site
- All Sponsor SOPs, are adhered to in addition to the SOPs of the participating centre if different
- Assist with investigations into any alleged research misconduct undertaken by or on behalf of the Sponsor
- Make necessary provision for archiving of essential documents

I confirm that I have read and understood my responsibilities as listed above  
CI Initials:  
Date:
### Roles & Responsibilities of Chief Investigator Agreement

**Date**

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<th>Signature:</th>
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<tr>
<th>Sponsor Representative:</th>
<th>Chief Investigator:</th>
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I have read the above and agree to adhere to these responsibilities for the study stated above.

Chief Investigator Declaration

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HHS Trust
University Hospitals
SHN