University of Leicester and University Hospitals of Leicester NHS Trust joint research support office standard operating procedures

University of Leicester Research Governance Office

Process to Ensure that NHS Permission is Received for Research Sponsored by the University of Leicester
SOP S-1006 UoL

Version 4.0, September 2023

Office Base

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Effective date: October 2023

This SOP will be implemented in line with this document's effective date for all UoL Sponsored research still in set up. For active clinical research that is already in the recruitment phase (or further) at the time of implementation, this SOP must be implemented within 3 months of the effective date.

1.0 Introduction & Scope

This Standard Operating Procedure (SOP) applies to all research studies sponsored by the University of Leicester (UoL) and describes the process used by the UoL to ensure that confirmation of capacity & capability (C&C) is received from each participating **NHS research site** before any research activity commences at the site. Please note this is not applicable to sites which are not conducting research activity e.g. Participant Identification Centres (PICs).

It is expected that by issuing confirmation of C&C, the participating site confirms that:

- They are able to conduct the study to appropriate standards and in accordance with the protocol.
- They have carried out the appropriate checks to satisfy its responsibilities as a Care Organisation under current legislation.

Should any clinical negligence occur at a participating site as part of the study it will be covered by the NHS indemnity schemes or by independent contractors' professional indemnity insurance.

Failure to comply with this SOP may result in Sponsorship being revoked.

2.0 Procedure

The Sponsor review process will identify whether a study intends to be conducted in one site (single site) or in numerous sites (multi-site). It will also identify which agreements may need to be put in place between UoL and the participating organisation. For guidance on contracts which don't relate to setting up a NHS organisation as a research site, please refer to the contracts SOP (S-1005). Where necessary, details of the relevant agreements required this will be included in the Sponsor Risk Assessment.

Where there is a requirement to add additional sites to a study (applicable to both single or multi-centre studies) this must be discussed with, and agreed by, the Sponsor. Where applicable, the risk assessment for the study may require updating.

2.1. Single Site Study

Where a study is taking place in a single site, confirmation of C&C must be obtained from the site to confirm site approval for study activities to commence. This must be in place before Sponsor Green Light (SGL) will be granted. Evidence of confirmation of C&C and SGL must be retained in the Trial Master File (TMF) and Investigator Site File (where relevant).

2.2. Multi-site study

Where a study is taking place in more than one site, confirmation of C&C must be obtained from each site to confirm site approval for the study activities to commence. This must be in place before site-specific SGL will be granted. Evidence of confirmation of C&C and SGL must be retained in the TMF and ISF.

2.3. NHS Site Agreements

The UoL RGO will facilitate and provide guidance on the development of the appropriate agreement to be sent to the NHS site(s), this will likely occur as part of the Sponsor review process. Typically, this will be either an Organisational Information Document (OID), a standard model Non-Commercial Agreement (mNCA) (where the study falls into the top 4 filter questions within IRAS, and/or a model Non-Commercial PIC Agreement (this may sit either between the Sponsor or the lead site and the PIC depending on the nature of the study. Different sections, and the various appendices within the agreements, may or may not require completing depending on whether funds are or aren't being transferred from the Sponsor to the NHS site, and whether any additional/supporting agreements e.g. data sharing or material transfer agreement will also be in place.

The host NHS site should finalise, date and sign the agreements prior to confirming C&C. The Head of Research Governance, or their delegate are authorised to sign these agreements on behalf of the UoL. Once fully signed, copies must be retained; in the ISF at the NHS site, by the relevant NHS R&D/I Offices and in the TMF.

Where necessary, the UoL RGO will liaise with, and will send draft and final agreements, along with any necessary supporting documentation, to any other relevant department(s) e.g. contracts, in RED.

3.0 Responsibilities

Responsibility	Undertaken by	Activity
Sponsor	Head of Research Governance or delegate	Ensure that the Chief Investigator (CI) understands the following before a study commences at a site; a) The relevant R&D/I office must be informed of the intention to conduct a study at a site. b) Confirmation of C&C must be obtained from each participating research site. c) Only once confirmation of C&C has been received will the Sponsor issue site-specific Sponsor Green Light for the study to commence.
Sponsor/CI	Head of Research Governance or delegate/CI/ Principal Investigator	a) Ensure the Sponsor are notified of site confirmation of C&C. b) File a copy of the confirmation of C&C in the TMF/ISF
Sponsor	Head of Research Governance or delegate	Confirm receipt of confirmation of C&C and issue site specific SGL
Sponsor	Head of Research Governance or delegate	Track any changes to confirmation of capacity and capability following amendments/pauses/suspensions noting any relevant actions required.

4.0 Development and approval record for this document

This table is used to track the development and approval of the document.

Author	Job title	Reviewed by	Approved by	Date approved
Cat Taylor	Head of Research Governance	UoL Research Sponsorship Management and Operation Group (RSMOG)	Professor Nigel Brunskill 	28/09/2023

5.0 Review record

This table is used to track the changes made on revised/reviewed versions.

Date	Issue number	Reviewed by	Description of changes (If any)
August 2015	2	Wendy Gamble	Amended to bring in line with Sponsor processes, addition of Loughborough to front page
Oct 2016	3	Diane Delahooke	Amended to bring in line with HRA changes/confirmation of capacity & capability from site R&I.
Sept 2021	3.1	Cat Taylor	Administrative changes
Sept 2023	4.0	Cat Taylor	Administrative and formatting changes to improve accessibility of SOP. Streamlining of information which is contained in other SOPs Update to the responsibilities table Removal and monitoring and audit criteria table Change to review period from every 2 to every 3 years