UNIVERSITY OF LEICESTER
&
UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST

JOINT RESEARCH & DEVELOPMENT SUPPORT OFFICE

STANDARD OPERATING PROCEDURES

University of Leicester (UoL) Research Governance Office
SOP S-1006 UoL

Version 3.1 September 2021

Process to Ensure that NHS Permission is Received for Research Sponsored by the University of Leicester

OFFICE BASE

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Effective Date: October 2021

1 Introduction

This Standard Operating Procedure (SOP) describes the process used by the University of Leicester (UoL) to ensure that copies of the NHS confirmation of capacity & capability for each Participating Organisation are received by the Chief Investigator (CI) before any research activity commences.

The outcome is that the UoL, when acting as Sponsor, has confirmed that the CI has received permission from all participating organisations prior to any research activity commencing.

It is expected that by issuing confirmation of capacity & capability, the Participating Organisation confirms that:

- The Participating Organisation is able to conduct the Study to appropriate standards and in accordance with the protocol.
- The Participating Organisation has carried out appropriate checks to satisfy its responsibilities as a Care Organisation under current legislation.
- Any clinical negligence at that Participating Organisation which occurs as part of the Study will be covered by NHS indemnity schemes or by independent contractors' professional indemnity insurance.

2 Scope

This SOP applies to all research studies sponsored by the University of Leicester.

3 Procedure

The Sponsor review process includes identifying whether it is proposed that a study will be conducted in just one site (single site) or in numerous sites (multi-site). This assessment will be included in the Sponsor Risk Assessment.

3.1 Single Site Study

Where a study is taking place in a single site, R&I confirmation of capacity & capability email will need to be obtained from the site to confirm their approval for study activities to commence at that site.

The R&I confirmation of capacity & capability must be in place before the Sponsor Green Light can be given.

Where there is a requirement to change a single site study into a multi-site once an 'in-principle' or 'confirmed' sponsor agreement has been received, the Chief Investigator must approach the Sponsor to discuss the implications before any applications are made to additional sites. There may be a requirement to reassess the Sponsor risk assessment, and there will be additional contractual agreements required.

Failure to do so may result in the UoL withdrawing Sponsor agreement.

3.2 Multi-site study

When the UoL agrees to sponsor a multi-site study, the risk assessment will take into account the additional requirements of managing research across all sites. A list of the intended participating sites will be required as part of the documentation.

The CI is expected to maintain a Trial Master File which must contain copies of all documentation submitted for the approval of each additional site. No activity must commence within the participating sites until a letter or email has been received from the site confirming capacity and capability at that site. Copies of all applications to participating sites and approval letters must be sent to the Sponsor.

Where there is a requirement to add to the additional sites initially declared at initial Sponsor review, the CI must discuss the implications with the Sponsor before any applications are made to additional sites. There may be a requirement to reassess the Sponsor risk assessment, and there will be additional contractual agreements required.

Failure to do so may result in the UoL withdrawing Sponsor agreement.

4 Responsibilities

	Responsibility	Undertaken by	Activity
1	Sponsor	Research Governance Manager or delegate	Ensure that the CI understands before a Study commences at a site that: a) The Principal Investigator (PI) for each site is expected to apply for and obtain confirmation of capacity & capability for that site. Where there is no PI / "no local Investigator", then the CI is expected to apply for confirmation of capacity & capability at each site. b) Only when the CI has received confirmation of capacity & capability for the site R&D dept and Sponsor Green Light is confirmed, can the Study begin at the Participating Organisation.
2	Sponsor / CI	Research Governance Manager or delegate / CI	a) Request a copy of confirmation of capacity & capability from the PI. b) File a copy in the Trial Master File (TMF). c) Inform the Sponsor of its receipt.
3	Sponsor	Research Governance Manager or delegate	Confirm receipt of confirmation of capacity & capability which enables the Study to commence at that Participating Organisation once the Sponsor Green Light is given
4	Sponsor	Research Governance Manager or delegate	Track any changes to confirmation of capacity & capability email/letter noting any relevant actions required.
5	Sponsor	Research Governance Manager or delegate	Ensure the CI is aware that the Study cannot commence at the site until Sponsor green light has been given.

5 Monitoring and Audit Criteria

Key Performance Indicator	Method of Assessment	Frequency	Lead
All research sponsored by UoL has appropriate contracts in place.	Included in the monitoring / audit programme.	Random audits / monitoring conducted on 10% of research activity. UoL is currently supported by UHL in this process.	Clinical Trials Monitor

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

6 Development and approval Record for this document

Author / Lead Officer:	Cat Taylor
Job Title:	Head of Research Assurance
Reviewed by:	UoL Research Management and Operations Group (RSMOG)
Approved by:	Professor Nigel Brunskill 
Date Approved	13/10/2021

7 Review Record

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

8 Distribution Record

Date	Name	Department	Received