University of Leicester Research Governance Office

Standard Operating Procedures

University of Leicester Research Governance Office

SOP S-1006 UoL

Agreements, Approvals and Contracts for Research Sponsored by the University of Leicester

Version 5.0, January 2025

Effective date: February 2025

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 all types of contracts and agreements necessary for a research study are in place.

2.0 Procedure

Advice regarding which agreements are required for the delivery of a research study can be sought from the Research Governance Office (RGO) or by reviewing the information provided on the HRA website and IRAS help section. Where relevant, the RGO will provide contact details for other research support departments who need to be included in the provision of agreements and contracts (i.e., Pre-Award and Contracts (PAC), Procurement).

In addition, the Sponsor Review process (SOP S-1002, and where necessary the Sponsor Risk Assessment (SOP S-1003)) will identify which agreements are required.

The drafting of agreements will be initiated and facilitated during the Sponsor Review process, and draft agreements should be provided as part of the application for Sponsorship (via Infonetica).

The RGO will facilitate the completion of agreements as part of the process for gaining external approvals.

The template agreements provided by the HRA and accessed via the IRAS help section must be used, and be used without modification.

2.1. NHS and non-NHS Site Agreements (i.e., research sites, PIC sites)

The RGO will facilitate, and provide guidance on, the development of the appropriate agreement to be sent to the participating 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 participating site should finalise, sign and date the agreements prior to confirming approval for the research at the site. The Head of Research Governance, or their delegate is authorised to sign these agreements on behalf of the UoL. When requesting Sponsor Green Light for a site, the fully executed agreement must be uploaded to Infonetica.

Once fully executed, a copy of the signed agreement must be;

- Uploaded to Worktribe (where relevant, this is not mandatory but is advised so that the PAC team have a record of site agreements)
- Retained by the relevant site R&D/I Office
- Retained in the Investigator Site File (ISF) at the relevant site
- Retained in the Trial Master File (TMF) at the lead site/coordinating centre
- Retained by the RGO.

2.1.1. Amendments to Site Agreements

Where an amendment to site agreement is required, a new or revised agreement should be submitted to the RGO for review, prior to being shared for approval by the relevant site R&D/I (or equivalent) office.

Where an amendment to an existing model Non-Commercial Agreement (mNCA) is required, an addendum or updated mNCA should be submitted to the RGO for review prior to being shared for approval by the relevant site R&D/I (or equivalent) office. Where applicable, the Pre-Award and Contracts (PAC) team will be notified. The RGO will support appropriate amendments/addendums to existing agreements and will manage the process to full execution.

The Head of Research Governance, or their delegate, are authorised to sign these documents on behalf of the UoL.

Once fully executed a copy of the signed agreement must be filled as per the information provided in section 2.1.

2.2. Non-NHS Contracts

As part of the grant application and award set-up, research teams are encouraged to identify any third-parties who may be involved in the research study. Additionally, the RGO Sponsor Review Process (S-1002) and Risk Assessment process (S-1003), may identify whether any agreements with third parties (e.g. funders, collaborators, laboratories and drug/device suppliers) are required. Details should be shared with the Pre-Award and Contracts (PAC) team within the Research and Enterprise Division (RED) via Worktribe so that appropriate agreement negotiations can begin.

Third-party Agreements are used to document and agree aspects of the relationship between the UoL and the third-party organisation(s), including, but not limited to:

- Roles and Responsibilities.
- Financial and legal considerations including indemnity.
- Termination considerations.
- Standards of service.
- Regulatory obligations including Data Protection.
- Intellectual property & publication considerations.
- Confidentiality considerations.

The completion of agreements, and any subsequent amendment should be managed in Worktribe. It is a requirement that before services commence, a written agreement between the UoL and the third-party be fully executed. In exceptional circumstances, where it is necessary for a third-party to commence activity prior to a fully executed (both initial and amended) agreement being in place, this must be agreed by all parties and evidence of said agreements/provisions retained (e.g. emails).

2.3. Site Approvals

2.3.1. Initial site approvals

2.3.1.1. Site Approval and Sponsor Green Light

Confirmation of site approval (i.e., Confirmation of Capacity and Capability, or equivalent) must be obtained from each site prior to study activities commencing at that site. This must be in place before Sponsor Green Light (SGL) will be granted.

Site Sponsor Green Light must be requested via Infonetica and evidence of site approval and a fully executed agreement must be provided (i.e., uploaded to the system) prior to the request being submitted. Sponsor Green Light will be issued via Infonetica and evidence of site approval and SGL must be retained in the TMF (for single-centre studies) and TMF and relevant ISF (for multi-centre studies).

2.4. Amendment Approval and Sponsor Green Light

Following the introduction of Infonetica and due to the complexity of amendment types, the UoL have implemented a pragmatic approach to issuing Sponsor Green Light for amendments.

In brief,

- CTIMP trial amendments are issued Sponsor Green Light for implementation on a per amendment and per site basis.
- For all other study types, the date of Sponsor Green Light is considered to be whichever of the following occurs first:
    - The 35th day following notification to a site of the amendment (where additional time has not been requested by the site), or
    - Upon receipt of approval (or of 'no objection') from a site whether this is within the 35 day notification period or later (where additional time has been requested by the site).

When an amendment is reviewed by the RGO, the outcome of the review and the requirement to request Sponsor Green Light (or not) will be communicated via Infonetica.

NB. The addition of a new research site will always require a Site Sponsor Green Light to be requested.

NB. Where a contract/agreement is amended as a consequence, the fully executed agreement must be uploaded as part of the Amendment Sponsor Green Light request.

For further details on this process, please refer to SOP 1018 .

3.0 Responsibilities

Responsibility	Undertaken by	Activity
Sponsor	Head of Research Governance or delegate	Confirm the necessity for, or the amendment to, site and/or third-party Agreements
Sponsor/CI/PAC	CI or delegate/PAC	Ensure non-NHS contract requests (both initial and amendment) are raised and managed within Worktribe
UoL RGO/PAC	Head of Research Governance, or delegate /PAC	Ensure that all third-party agreements and amendments are drafted, reviewed, negotiated and approved, ensuring that responsibilities of all parties are accurately documented and where required the relevant staff are consulted during negotiations.
Sponsor	Head of Research Governance or delegate	Ensure that the Chief Investigator (CI) understands the following before a study commences; • General provisions • Appropriate contracts must be executed prior to research activity taking place Site provisions • The relevant R&D/I office must be informed of the intention to conduct a study at a site. • Confirmation of site approval must be obtained from each participating research site

Responsibility	Undertaken by	Activity
		• Only once site approval has been received will the Sponsor issue site-specific Sponsor Green Light for the study to commence. • Appropriate site approvals are received following amendments
Sponsor/CI	CI/ Principal Investigator or delegate	• Ensure the Sponsor are notified of site Confirmation of Capacity and Capability, or equivalent). • File a copy of the confirmation of C&C, or equivalent in the TMF/ISF
Sponsor	Head of Research Governance or delegate	Confirm receipt of site Confirmation of Capacity and Capability, or equivalent) and issue site specific SGL
Sponsor	Head of Research Governance or delegate	Track any changes to site Confirmation of Capacity and Capability, or equivalent) 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 	03/02/2025

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
January 2025	5.0	Cat Taylor	• Major updates to SOP • Addition of information relating to non-NHS contracts as such making SOP S-1005 and S-1031 obsolete. • • Updates to wording around site and amendment approvals • Update to the responsibilities table • Removal of office address from front page