

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

University of Leicester Research Governance Office

SOP S-1005 UoL

Version 4.0 September 2023

**Sponsor Contracts Management for Research Sponsored by
University of Leicester**

Office Base

Research Governance Office
Academic Department, Ground Floor
Leicester General Hospital
Gwendolen Road
Leicester
LE5 4PW

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 and Scope

This Standard Operating Procedure (SOP) describes the procedures used by the University of Leicester (UoL) Research Governance Office (RGO) when providing and managing agreements with Third Parties, where the University is the Sponsor under the relevant regulatory requirements.

Clinical research studies often involve agreements with external organisations, such as funders, research sites, collaborators, laboratories and drug/device suppliers. Where policy or legislation necessitates that a clinical research study has a Sponsor, it is the requirement of a Sponsor to document clear agreements with relevant external parties. These should describe tasks, duties, functions between parties and, where relevant, any required standards of service.

As the agreements required can vary considerably, this SOP aims to provide considerations which are generally applicable.

The outcome is that the UoL is able to manage the ongoing contractual process throughout the duration of a research study.

2.0 Procedure

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. Details should be shared with the Research Grants Support Managers or Contracts Managers within the Research and Enterprise Division (RED) so that appropriate agreement negotiations can begin.

Third Party Agreements include, but are not limited to those between:

- The UoL and Funder(s).
- The UoL and Organisations providing a service (e.g. statistical support, Contract Research Organisation, Monitoring, Clinical Trial Units etc).
- The UoL and providers of medicinal products or equipment.

And include

- Contracts
- Clinical trial agreements
- Service level agreements
- Roles and responsibilities/delegation of responsibilities documents
- Forms of work or similar documents.

The form of the third-party agreement should be proportionate to the level of risk associated with the study and the type/nature of the other organisation(s) involved. It is expected that the UoL will use nationally approved standard templates where applicable and appropriate.

It is a requirement that before services commence, a written agreement between the UoL and the Third Party be fully executed. Where it is necessary for a Third party to commence pre-trial set up activity, a letter of intent will be provided to allow these activities to begin.

The RGO Sponsor Review Process (S-1002) and Risk Assessment process (S-1003), will identify whether any further agreements are required e.g. a contract/agreement will be required between the UoL and all participating NHS sites (refer to SOP S-1006 NHS Permissions). Where necessary, the UoL RGO will forward details of Third Parties and NHS sites using the List of third-party Contracts/Site Agreements document to Research Grants Support Managers or to Contracts Managers within the Research and Enterprise Division (RED) for appropriate action.

2.1 Third Party/Vendor Agreements

Where Third Parties providing services, funding, equipment, medicinal products etc. have been identified, or where the clinical trial is solely funded by a public body, including but not limited to the NIHR, or a charitable organisation, details will be forwarded to the relevant team within RED.

Third Party Agreements will also be forwarded to the relevant team within RED if the clinical trial is funded or partly funded, including but not limited to the provision of the study drug or equipment, by a commercial entity and/or a commercial partner is seeking ownership or use of any resulting clinical trial data, results or any other form of intellectual property arising from the clinical trial.

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 agreements must be signed by all parties. Once fully signed, copies must be retained; by the relevant department within RED, by the third-party organisation and in the Trial Master File.

This SOP does not cover employment or Human Resources related contracts.

3.0 Responsibilities

Responsibility	Undertaken by	Activity
UoL RGO	Head of Research Governance or delegate	Confirm the necessity for third-party Agreements and inform the relevant departments within RED
UoL RGO	Head of Research Governance or delegate	Generate a Non-Commercial Model Agreement where there are no revisions required and no transfer of funds to NHS sites.

Responsibility	Undertaken by	Activity
UoL RGO/RED	Head of Research Governance, or delegate/RED	RGO to generate Non-Commercial Model Agreements where there are transfer of funds to NHS sites and to forward to RED for verification of financial arrangements. Following approval by RED, Head of Research Governance, or delegate, to manage execution of signatures.
UoL RGO/RED	Head of Research Governance, or delegate/RED	Ensure that all third-party agreements are drafted, reviewed, negotiated and approved, ensuring that responsibilities of all parties are accurately documented.
UoL RGO/RED	Head of Research Governance, or delegate/RED	Ensure that all relevant academic and departmental staff involved in the project, and University support staff are adequately consulted during negotiations and prior to the contract execution.
UoL RGO/RED	Head of Research Governance/RED	Ensure third-party Agreements are filed/retained in accordance with UoL policies.

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)
Oct 2013	2	Wendy Gamble	Document 1 revised following review of Sponsor processes
Jan 2017	3	Contracts & Grants team & RGO	SOP reviewed by RSS and updated to reflect current practice and Statement of Activities.
Sept 2021	3.1	Cat Taylor	Administrative changes
September 2023	4.0	Cat Taylor	Administrative and formatting changes to improve accessibility of SOP. Correction to the use of the Organisational Information Document in Place of the Statement of Activities. Edits to when relevant departments within RED need to be involved in agreements Removal of monitoring and audit criteria