UNIVERSITY OF LEICESTER
&
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JOINT RESEARCH & DEVELOPMENT SUPPORT OFFICE

STANDARD OPERATING PROCEDURES

University of Leicester (UoL) Research Governance Office SOP S-1005 UoL

Version 3.1 September 2021

Sponsor Contracts Management for Research Sponsored by University of Leicester

OFFICE BASE

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Effective Date: October 2021

1 Introduction

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

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

It is essential that clear agreements describing allocation of roles and responsibilities are reached and documented prior to any Study-related procedure commencing. Where it is necessary for a Third Party to commence pre-trial set up activity, a letter of intent will be provided.

2 Procedure

It is expected that during the UoL Sponsor Green Light and Risk Assessment process, Third Parties and NHS sites will be identified in order for appropriate agreement negotiations to begin. 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 UoL Research Governance Office 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 in Research Support Services (RSS), within the Research and Enterprise Division (RED) for appropriate action.

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

- The UoL and Participating Organisation(s) – Research sites.
- The UoL and another Co-Sponsor or Joint Sponsor.
- The UoL and Funder (s).
- The UoL and Organisations providing a service (e.g. statistical support, CRO, Monitoring, CTU etc).
- The UoL and providers of medicinal products or equipment.

Third Party Agreements include contracts, clinical trial agreements, service level agreements, roles and 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.

2.1 NHS Site Agreements – no transfer of funds

Where it has been confirmed by the appropriate office within RED that there is no transfer of funds from the UoL as Sponsor to an NHS Site, the UoL Research Governance Office will generate either a Statement of Activities or a standard Non-Commercial Model Agreement (mNCA) (mandatory for CTIMP studies) to be sent to the NHS site.
Where the Statement of Activities is used, this is finalised and dated when the host NHS site confirms capacity and capability.

Where a mNCA is used the Research Governance Manager or their delegate is authorised to sign these agreements on behalf of the UoL. Three (3) contracts will be submitted to the NHS site for signature. Once fully signed, a copy must be placed in the Investigator Site File at the NHS site, one (1) original to be kept by the NHS site R&D Office, one (1) original to be placed in the Trial Master File and one (1) original to be placed in the Sponsor file. A copy will be sent to RED.

2.2 NHS Site Agreements – with transfer of funds

Where there are funds to be transferred from the UoL as Sponsor to an NHS Site, the UoL Research Governance Office will generate either a Statement of Activities or a standard mNCA (mandatory for CTIMPs studies) and populate the details including the Finance section.

Where the Statement of Activities is used, this is finalised and dated when the host NHS site confirms capacity and capability.

Where a mNCA is used the UoL Research Governance Office will send the draft agreement to the relevant team within RSS for approval, along with supporting documentation.

The Research Grants Support Team or the Contracts Team will endeavour to reply to such requests within five (5) working days by way of email reply to the Research Governance Office.

Once approval is received from the appropriate team within RSS, the UoL Governance Office will manage the agreement process, from draft submission to the NHS site to the point of execution for signatures.

The Research Governance Manager or their delegate is authorised to sign these agreements on behalf of the UoL.

Once fully signed, a copy must be placed in the Investigator Site File at the NHS site, one (1) original to be kept by the NHS site R&D Office, one (1) original to be placed in the Trial Master File and one (1) original to be placed in the Sponsor file. A copy will be sent to RSS and saved on the shared X drive.

2.3 Third Party / Vendor Agreements

Where Third Parties providing services, funding, equipment, medicinal products etc. have been identified during the Sponsor Risk Assessment and Green Light Process, details will be forwarded using the List of Third Party Contracts / Site Agreements document to either the Research Grants Support team or the Contracts team within RSS.

Third Party Agreements will be forwarded to the Research Grants Support Team within RSS if the clinical trial is solely funded by a public body, including but not limited to the NIHR, or a charitable organisation.

Third Party Agreements will be forwarded to the Contracts Team within RSS 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.

Two (2) originals must be signed by all parties. One (1) original to be kept by RED, one (1) original for the Third Party organisation, with copies sent to the Research Governance Office for inclusion in the trial specific Sponsor file and to the Chief Investigator for inclusion in the Trial Master File.

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

3 Responsibilities

	Responsibility	Undertaken by	Activity
1	UoL Research Governance Office	Research Governance Manager or delegate	Confirm the necessity for Third Party Agreements during the Sponsor Risk Assessment and Green Light Process forwarding the List of Third Party Contracts / Site Agreements document to RSS.
2	UoL Research Governance Office	Research Governance Manager or delegate	Generate a Non-Commercial Model Agreement where there are no revisions required and no transfer of funds to NHS sites.
3	UoL Research Governance Office / RSS	Research Governance Manager / staff in RSS	Research Governance Office 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, Research Governance Manager or delegate to manage execution of signatures.
4	UoL RSS	Staff in RSS	Ensure that all Third Party agreements are drafted, reviewed, negotiated and approved, ensuring that responsibilities of all parties are accurately documented.
5	UoL RSS	Staff in RSS	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.
6	UoL RSS	Research Governance Manager / RSS	Ensure Third Party Agreements are filed / retained in accordance with UoL policies.

4 Monitoring and Audit Criteria

Key Performance Indicator	Method of Assessment	Frequency	Key Performance Indicator
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.	Research Governance Manager or their Delegate

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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

5 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

6 Review Record

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

7 Distribution Record

Date	Name	Department	Received