



UNIVERSITY OF  
LEICESTER

**University of Leicester Research Governance Office  
Standard Operating Procedures**

**SOP S-1031 UoL**

**Managing Amendments to Contracts for Research Sponsored by  
University of Leicester**

**Version 2.2, January 2024**

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

Effective Date: January 2024

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 when managing amendments to contracts relating to research Sponsored by the University of Leicester (UoL).

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

## 2.0 Procedure

It is expected that where appropriate during any stage of the study, required revisions to existing Third Party and NHS site agreements will be identified in order for appropriate negotiations to begin.

It is a requirement that before any changes to contracted services commence, an amended agreement between the UoL and the Third Party must be fully executed. In exceptional circumstances, and where it is necessary for a Third party to commence revised activity prior to a fully executed amended agreement, a letter of intent will be provided by a member of the Research Support Services (RSS) team, which is within the Research and Enterprise Division (RED), to allow these activities to begin.

The UoL Research Governance Office will forward details of amendments required to existing Third Party and NHS site agreements, using the List of Third Party Contracts / Site Agreements document, to Grants Managers and Contracts Managers within RSS for appropriate action.

### 2.1 NHS Site Agreements

Where an amendment to a Statement of Activities is required, a new updated Statement of Activities should be submitted to the host R&I/R&D office together with the amendment for approval by the UoL Research Governance Office.

Where an amendment to a standard model Non-Commercial Agreement (mNCA) is required, the UoL Research Governance Office will provide supporting documentation for the changes/amendments required to Grants Support Managers and/or Contracts Manager within RSS as appropriate.

RSS or Research Governance Office will generate appropriate amendments to existing agreements, forwarding the revised agreement to the UoL Research Governance Office who will then manage the contract process to full execution. The Research Governance Manager or their delegate is authorised to sign these amendments on behalf of the UoL.

Three (3) originals of the amendment will be submitted to the NHS site for signature. Once fully signed, one (1) original should be kept by the NHS site R&D Office, one (1) original should be placed in the Trial Master File and one (1) original should be placed in the Sponsor file. A copy must be placed in the

Investigator Site File at the NHS site and a copy will be sent to RSS for saving on the shared X Drive.

## 2.2 Third Party/Vendor Agreements

Where amendments to agreements with Third Parties providing services, funding, equipment, medicinal products etc. have been identified, details will be forwarded to RSS.

RSS will generate appropriate amendments to existing agreements. Two (2) originals must be signed by all parties. Once fully signed, one (1) original should be sent to the Research Governance Office for inclusion in the trial specific Sponsor file, and one (1) original should be sent to the Third Party organisation. Copies should be sent to the Chief Investigator, or their delegate, for inclusion in the Trial Master File and to RSS for saving on the shared X drive.

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

## 3.0 Responsibilities

Responsibility	Undertaken by	Activity
UoL Research Governance Office	Head of Research Governance or delegate	Confirm the necessity for amendments to Third Party Agreements throughout the Sponsor Risk Assessment and Green Light Process for amendments, forwarding the List of Third Party Contracts / Site Agreements document to RSS.
UoL Research Governance Office/ RSS	Head of Research Governance or delegate/staff in RSS	RSS or Research Governance Office to generate amendment document for Non-Commercial Model Agreements and Statement of Activities where there are revisions. Head of Research Governance, or delegate, to manage execution of signatures.
UoL RSS	Staff in RSS	To ensure that all Third Party contract amendments are drafted, reviewed, negotiated and approved.
UoL RSS	Staff in RSS	To 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 amendment execution.
UoL Research Governance Office	Head of Research Governance/RSS	To ensure amendments to 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 Management and Operations Group (RSMOG)	Professor Nigel Brunskill 	19/01/2024

## 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)
Jan 2017	2	Research Governance Office and Contracts Team	Logo and address updated. Updated to reflect current practices within RED and HRA.
Sept 2021	2.1	Cat Taylor	Administrative changes
October 2023	2.2	Cat Taylor	Administrative Changes Minor updates to wording Removed monitoring and audit criteria Removed distribution record