



**UNIVERSITY OF LEICESTER, UNIVERSITY OF LOUGHBOROUGH
&
UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST
JOINT RESEARCH & DEVELOPMENT SUPPORT OFFICE
STANDARD OPERATING PROCEDURES**

**University of Leicester (UoL) Research Governance Office
SOP S-1031 UoL**

Version 2, January 2017

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

OFFICE BASE

Research Governance Office
Research & Enterprise Division
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Effective Date: April 2017



1 Introduction

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

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

2 Scope

This SOP applies to all contracts relating to research sponsored by the University of Leicester that require amendment.

3 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.

3.1 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 Non-Commercial Model 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.

3.2 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 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.

4 Responsibilities


| Responsibility Undertaken by | | Activity | |
|------------------------------|--------------------------------------|--|--|
| 1 | UoL Research Governance Office | Research Governance Manager 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. |
| 2 | UoL Research Governance Office / RSS | Research Governance Manager 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. Research Governance Manager or delegate to manage execution of signatures. |
| 3 | UoL RSS | Staff in RSS | To ensure that all Third Party contract amendments are drafted, reviewed, negotiated and approved. |
| 4 | 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. |
| 5 | UoL Research Governance Office | Research Governance Manager / RSS | To ensure amendments to Third Party Agreements are filed / retained in accordance with UoL policies. |

5 Monitoring and Audit Criteria

| Key Performance Indicators | Method of Assessment | Frequency | Lead |
|---|---|---|---|
| All research sponsored by UoL has appropriate Risk Assessment | Included in the monitoring / audit programme. | Random audits / monitoring conducted on 10% of research activity. | Research Governance Manager or their Delegate |

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

Development and approval Record for this document

| | |
|-----------------------------|--|
| Author/Lead Officer: | Wendy Gamble |
| Job Title: | Research Governance Manager |
| Reviewed by: | Research Sponsorship Management and Operations Group |
| Approved by: | Professor Nigel Brunskill  |
| Date Approved: | 10/04/2017 |

Review Record

| 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. |

Distribution Record

| Date | Name | Department | Received |
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