



UNIVERSITY OF
LEICESTER

**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-1026 UoL**

Version 3, October 2016

**Sponsor Green Light Process for Amendments to Research
Sponsored by the University of Leicester (UoL)**

OFFICE BASE

Research Governance Office
Research & Enterprise Division
University of Leicester
Fielding Johnson Building
University Road
Leicester
LE1 7RH

Effective Date: April 2017



1. INTRODUCTION

This Standard Operating Procedure (SOP) describes the procedures used by the Research Governance Office within University of Leicester (UoL) when completing the Sponsor Green Light Process for amendments to research that has previously received formal approval.

The outcome is that the Research Governance Office is able to confirm that the UoL has conducted a revised Risk Assessment and Sponsor review and is able to continue to act as research Sponsor.

2. SCOPE

This SOP applies to all research where the UoL acts as Sponsor.

3. CATEGORIES OF AMENDMENTS

Amendments are viewed as changes to any research documentation that has been reviewed and approved by regulatory authorities and the Sponsor.

There are essentially two types of amendments.

- Substantial amendments
- Non-Substantial amendments

Both types of amendments require a different process as detailed below.

It is important to note that ANY change to ANY documentation, including administrative changes in a research study categorised as a Clinical Trial of an Investigational Medicinal product (CTIMP) must be sent to the Sponsor before the changes are implemented, or submitted to regulatory authorities, except in cases of Urgent Safety Measures which is discussed in detail in [SOP S-1029 UoL](#).

3.1 Substantial Amendments

A substantial amendment is a change that is likely to have a significant impact on:

- The safety, or physical or mental integrity of the trial subjects
- The scientific value of the study
- The conduct or management of the study
- The quality or safety of the Investigational Medicinal Product

It is the responsibility of the Sponsor to decide whether or not an amendment is substantial. In addition, the Sponsor must decide whether or not the amendment requires authorisation from the MHRA as well as a favourable opinion from the Research Ethics Committee and HRA approval.

A list of amendments that require authorisation from the MHRA can be found at [Appendix 1](#). A list of amendments that require both authorisation from the MHRA and a REC

Favourable Opinion can be found at [Appendix 2](#). A list of amendments that require Favourable Opinion from the REC can be found at [Appendix 3](#). A list of amendments that do not require notification to REC or MHRA but do still require notification to the Sponsor can be found at [Appendix 4](#).

In addition, the HRA process requires that each amendment is given a categorisation. Details of these categories can be found on the HRA Website (www.hra.nhs.uk).

In addition to the MHRA and REC/HRA, the Host Organisation R&D / R&I Office may also be required to review amendments prior to implementation at the NHS site. It is therefore essential that a review of the NHS R&D / R&I SOPs is undertaken for each site. This should be noted during the Sponsor Amendment Green Light process and recorded on the Sponsor Amendment Green Light – Multi-Site documentation ([Appendix 5](#)).

3.1.1 Process for Substantial Amendments

All amendments must be sent to the Research Governance Office for Sponsor review. All documentation to be amended along with relevant amendment forms must be included in order for the amendment to be regarded as valid. The Research Governance Manager or their delegate will review the documentation and will confirm that the amendment is 'substantial'. This process may take up to 14 calendar days.

The Research Governance Manager or their delegate will review the amendment documentation, and will revise the initial Sponsor Risk Assessment form or Sponsor review documentation as necessary. This may require further review by the Research Sponsorship Management & Operations Group (RSMOG) or the Research Sponsorship Committee (RSC) if the amendment affects the risk outcome in accordance with [SOP S-1003 UoL Sponsor Risk Assessment](#).

If an amendment includes the addition of new sites or Third Parties, the relevant [SOP S-1025 UoL Sponsor Green Light Process](#) and / or [SOP S-1005 UoL Contracts](#) will be implemented.

If necessary, a face-to-face meeting with the Chief Investigator and / or study personnel will be requested to discuss the proposed amendment in detail prior to Sponsor Amendment Green Light confirmation.

The Research Governance Manager or their delegate will complete the Sponsor Amendment Green Light documentation or relevant entities/ workflows in the EDGE system during the review of amendment documentation. When the documentation review and revised risk assessment has been completed, and relevant action has been taken or is in progress to mitigate any additional risk identified, the Research Governance Manager will confirm to the Chief Investigator or their delegate the Sponsor's permission to submit the amendment to relevant regulatory authorities.

Sponsor Amendment Green Light will be confirmed on receipt of documentary evidence that the relevant permissions, any additional contracts or agreements are in place, confirmation of indemnity and regulatory authority approvals have been received. The Sponsor Amendment Green Light document ([Appendix 6](#)) or relevant entities/ workflows in the EDGE system must be retained in the Sponsor file, along with copies of all relevant documentation. A Sponsor Amendment Green Light confirmation email/ letter will be sent allowing implementation of the amendment to take place.

3.2 Non-Substantial Amendments

Research involving Clinical Trials of Investigational Medicinal Product

ANY change to ANY documentation, including administrative changes in a research study

categorised as a Clinical Trial of an Investigational Medicinal product (CTIMP) must be sent to the Sponsor before the changes are implemented, or submitted to regulatory authorities, except in cases of Urgent Safety Measures which is discussed in detail in [SOP S-1029 UoL](#).

Research not involving Investigational Medicinal Products

Where amendments are deemed to be Non-Substantial/Administrative/Minor as listed in [Appendix 3](#), and not for research involving Clinical Trials of Investigational Medicinal Products, the amendment may be submitted to the REC/ HRA & NHS Trust R&D / R&I offices for favourable opinion/ approval / acknowledgement as necessary ensuring that the UoL as Sponsor is copied into any correspondence using uolsponsor@le.ac.uk. A Non Substantial amendment form must be completed as part of the process which is available on the HRA website. At the current time, all non-substantial amendments are required to be submitted to the HRA for approval and categorisation, but it is recommended that the HRA is referenced prior to submission as there are plans to revise this process.

3.2.1 Process for Non-Substantial amendments

All amendments must be sent to the Research Governance Office for Sponsor review. All documentation to be amended along with relevant amendment forms must be included in order for it to be regarded as valid. The Research Governance Manager or their delegate will review the documentation and will confirm that the amendment is 'non- substantial' . This process may take up to 14 calendar days.

The Research Governance Manager or their delegate will review the amendment documentation, and will revise the initial Sponsor Risk Assessment form and Sponsor review documentation as necessary. This may require further review by the Research Sponsorship Management & Operations Group (RSMOG) or the Research Sponsorship Committee (RSC) if the amendment affects the risk outcome in accordance with [SOP S-1003 UoL Sponsor Risk Assessment](#).

If an amendment includes the addition of new sites or Third Parties, the relevant [SOP S-1014 UoL Sponsor Green Light Process](#) and / or [SOP S-1005 UoL Contracts](#) will be implemented.

If necessary a face-to-face meeting with the Chief Investigator and / or study personnel will be requested to discuss the proposed amendment in detail prior to Sponsor Amendment Green Light confirmation.

The Research Governance Manager or their delegate will complete the Sponsor Amendment Green Light document or relevant entities/ workflows in the EDGE system during the review of amendment documentation. When the documentation review and revised risk assessment has been completed, and relevant action has been taken or is in progress to mitigate any additional risk identified, the Research Governance Manager or delegate will confirm to the Chief Investigator or delegate, the Sponsor's permission to submit the amendment to relevant regulatory authorities.

Sponsor Amendment Green Light will be confirmed on receipt of documentary evidence that the relevant permissions and any additional contracts or agreements are in place, and confirmation of indemnity and regulatory authority approvals have been received. The Sponsor Amendment Green Light document (Appendix 6) must be retained in the Sponsor file, along with copies of all relevant documentation. A Sponsor Amendment Green Light confirmation email/ letter will be sent allowing implementation of the amendment to take place

It is important to remember that the Sponsor must be sent a copy of any revised study documentation and details of changes in key personnel during the lifecycle of a research

study.

4. NON- COMPLIANCE

Where it is identified that the processes detailed above have not been followed, the [SOP S-1016 UoL Non-Compliance](#) will be implemented at a minimum of a Major finding.

5. RESPONSIBILITIES

Complete Study Risk Assessment Form

Responsibility	Undertaken by	Activity
1 Chief Investigator or their delegate	Chief Investigator or their delegate	Submit all documentation relating to the amendment to the Sponsor UOLsponsor@le.ac.uk .
2 Sponsor	Research Governance Manager or delegate	Commence completion of Risk Assessment Form and Sponsor review.
3 Sponsor	Research Governance Manager or delegate	Completion of Sponsor Amendment Green Light – First Site and completion of Sponsor Amendment Green Light – Multi-Centre.
4 Sponsor & Chief Investigator	Research Governance Manager & Chief Investigator	Ensure no implementation of amended documentation commences prior to receipt of Sponsor Green Light email/letter.


6. 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)
April 2015	2	UoL RSMOG	Minor administrative changes to logos and text, date and version changes to footer. Addition of Loughborough University to front page.
Oct 2016	3	Diane Delahooke	Change of logo and made consistent with UHL, references to HRA and EDGE added.

Distribution Record

Date	Name	Department	Received