



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

**University of Leicester (UoL) Research Governance Office
SOP S-1018 UoL**

Version 3.1 September 2021

**Process for Sponsor Approval of Amendments or Additions to
Documents for Studies already Sponsored by UoL**

OFFICE BASE

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

Effective Date: October 2021

1 Introduction

This SOP details the University of Leicester (UoL) procedures for managing amendments in research studies where the UoL is acting as the Sponsor Organisation.

It is recognised that from time to time approved documentation used in a research study requires amendment. In addition it is sometimes the case that additional documents are required.

Before amendments to any study documentation are implemented, the Sponsor must review and provide authorisation for submission to the relevant regulatory bodies. i.e. Medicines & Healthcare Regulatory Agency (MHRA), Health Research Authority (HRA), Research Ethics Committees (REC) and NHS Trusts (R&D / R&I).

In cases where amendments are as a direct result of urgent safety measures, the approval can be obtained retrospectively. Urgent safety measures are covered in **SOP S-1009 UoL**.

2 Scope

This SOP applies to all research where the UoL are acting as the Sponsor organisation.

3 Definitions

Essentially from a regulatory perspective there are two types of amendments, but the Sponsor must review all amendments, including those that are simple administrative changes.

3.1 Substantial Amendments:

Substantial amendments to the conduct of a research study may arise from changes to the protocol or from new information relating to the scientific documents in support of the study. Amendments to the study are regarded as 'substantial' where they are likely to have a significant impact on

1. The safety or physical or mental integrity of the subjects, or
2. The scientific value of the study, or
3. The quality or safety or any IMP used in the study, or
4. The conduct or management of the study

For further examples of substantial amendments please see HRA amendments update link.

3.2 Non-Substantial Amendments:

Non-Substantial amendments can be defined as amendments that do not have any significant implications to:

- the conduct of the research

- the participants of the research
- scientific value
- management

Examples of Non-Substantial amendments can be found on the [HRA website](#).

3.3 All other amendments

Other amendments may include corrections to spelling, contact details of the research team members or Clinical Research Assistant / Officer / Organisation or anything not covered by either Substantial or Non-Substantial definitions.

4 Procedures

All proposed amendments to any research documentation must be reviewed and authorised by the Sponsor prior to submission to any regulatory agency or implementation, with the exception of Urgent Safety Measures. It is the responsibility of the Sponsor to make the final decision as to the nature of the amendment.

4.1 Substantial Amendments

All documentation relating to the proposed substantial amendment must be submitted to the Sponsor prior to submission to the MHRA, HRA, REC or Trust R&D/ R&I Office. The Sponsor will undertake a review of the documents and ask for further information or clarification as necessary. An initial review will be completed within 14 days of submission of a valid amendment to the Sponsor.

Where there are changes to the protocol, to planned recruitment, addition of sites or equipment additional approvals will be required from the relevant support departments before Sponsor authorisation is given. E.g. Finance, Pharmacy, Medical Physics, Insurance Office etc.

The Sponsor will complete the Amendment Sponsor Green Light Process once all queries and revisions have been satisfied. The Sponsor will notify the Chief Investigator or Point of Contact that authorisation is given to proceed with the application to relevant regulatory authorities and will confirm the nature of the amendment.

The link here is for the [MHRA guidance](#) on how to submit amendments for Clinical Trials of Investigational Medicinal Products.

The link here is for [HRA Guidance](#) on how to submit amendments to the HRA and REC for both CTIMP studies and Non-CTIMP studies.

Multi-centre studies

In cases of Multi-centre studies, there is a requirement for each site to confirm or reject implementation of the amendment within set timeframes as indicated on the [HRA website](#). It is the Chief Investigator's responsibility to ensure that the Sponsor has received copies of relevant approvals and confirmation of capacity and capability in order for the Amendment Sponsor Green Light to be given. The Chief Investigator must ensure that amendments are not implemented at sites prior to receipt of the Amendment Sponsor Green Light.

4.2 Non-Substantial Amendments

All documentation relating to the proposed Non-Substantial amendment must be copied to the Sponsor in parallel to the submission to the HRA/ REC or Trust R&D / R&I Office as appropriate.

Further guidance on the submission of Non-Substantial amendments can be found at the links under Substantial Amendments.

4.3 All other amendments

All documentation not requiring regulatory approval under Substantial or Non-Substantial processes must be sent to the Sponsor for information purposes only, prior to implementation.

5 Urgent Safety Measures

In cases where Urgent Safety Measures (USM) are required, it is acknowledged that is not always appropriate to wait until Sponsor authorisation has been granted. In these cases, the amendment will be reviewed retrospectively. Urgent Safety Measures are also referenced in SOP S-1009 UoL.

The Sponsor must ensure that the REC & MHRA are notified of the USM immediately, and in any event within 3 days, that such a measure has been taken, and the reasons why it has been taken. Notice to the MHRA should initially be done by telephone and followed by notification in writing which must be sent within 3 days, setting out the reasons for the USM and the plan for further action.

6 Responsibilities

Responsibility	Undertaken by	Activity
1 Sponsor	Research Governance Manager or delegate	Confirm nature of amendment – Substantial, Non-Substantial, All other amendments or Urgent Safety Measures.
2 Chief Investigator	Chief Investigator or their delegate	Ensure all relevant amendment documentation submitted to the Sponsor for review and authorisation.
3 Sponsor	Research Governance Manager or delegate	Liaise with the Chief Investigator, during review of amendment documentation
4 Sponsor	Research Governance Manager or delegate	Confirm authorisation to Chief Investigator giving permission to submit to regulatory authorities as required or to implement amendment when it is not deemed a Substantial or Non-Substantial amendment

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

7 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

8 Review Record

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
April 2015	2	UoL RSMOG	SOP reviewed and revised to incorporate changes to logos, departmental titles and minor administrative changes to text, dates / footer. Also a Scope section added to document. Addition of Loughborough University to front page
Oct 2016	3	Diane Delahooke	Updated logo and reference made to HRA.
Sept 2021	3.1	Cat Taylor	Administrative changes

9 Distribution Record

Date	Name	Department	Received