LOUGHBOROUGH UNIVERSITY RESEARCH OFFICE
STANDARD OPERATING PROCEDURE

Loughborough University (LU) Research Office
SOP–1018 LU

Process for Sponsor Approval of Amendments or Additions to Documents for NHS Studies Sponsored by Loughborough University

Effective Date: January 2016

1.0 Introduction

This SOP details Loughborough University procedures for managing amendments in research studies where LU 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. Research Ethics Committees (REC) and NHS Trusts (R&D).

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 1009 LU.

1.1 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.

1.1.1 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 trial. Amendments to the trial 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 trial, or
3. The conduct or management of the trial

For further examples of substantial amendments please see NRES Guidance.

1.1.2 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 NRES website

1.1.3 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.

2.0 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.

2.1 Substantial Amendments

All documentation relating to the proposed substantial amendment must be submitted to the Sponsor prior to submission to the REC or Trust R&D 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 Approval 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 NRES guidance on how to submit amendments to the REC for Non-CTIMP studies.

Multi-centre studies

In cases of Multi-centre studies, there is a requirement for each site to approve amendments prior to implementation of the amendment. It is the Chief Investigator's responsibility to ensure that the Sponsor has received copies of relevant Trust R&D approval in order for the Amendment Sponsor Approval to be given. The Chief Investigator must ensure that amendments are not implemented at sites prior to receipt of the Amendment Sponsor Approval.

2.2 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 REC or Trust R&D Office as appropriate.

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

2.3 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.

2.4 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 1009 LU.

The Sponsor must ensure that the REC is 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.

3.0 Responsibilities

	Responsibility	Undertaken by	Activity
1	Sponsor	Research Governance Officer or delegate	Confirm nature of amendment – Substantial, Non-Substantial, All other amendments or Urgent Safety Measures.

	Responsibility	Undertaken by	Activity
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 Officer or delegate	Liaise with the Chief Investigator, during review of amendment documentation
4	Sponsor	Research Governance Officer 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

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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

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT		
Author / Lead Officer:	Jackie Green	**Job Title:** Research Governance Officer
Approved by:	**Ethics Committee**	**Date Approved: 5/2/16**

REVIEW RECORD			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**

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