LOUGHBOROUGH UNIVERSITY RESEARCH OFFICE
STANDARD OPERATING PROCEDURE

Loughborough University (LU) Research Office
SOP–1026 LU

Sponsor Approval Process for Amendments to NHS Research Sponsored by Loughborough University

Effective Date: January 2016

1.0 Introduction

This Standard Operating Procedure (SOP) describes the procedures used by the Research Governance Office within Loughborough University when completing the Sponsor Approval Process for amendments to research that has previously received formal approvals.

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

2.0 Scope

This SOP applies to all research where LU acts as Sponsor in accordance with the Research Governance Framework (v2. 2005).

3.0 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 must be sent to the Sponsor before the changes are implemented, or submitted to regulatory authorities, except in case of Urgent Safety Measures which is discussed in detail in SOP -1029 LU.

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

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 a Favourable opinion from the Research Ethics Committee.

A list of amendments that require both authorisation from the MHRA (where applicable) and a REC Favourable Opinion can be found at Appendix A. A list of amendments that require Favourable Opinion from the REC can be found at Appendix B.

In addition to the REC, the Host Organisation R&D Office may also require submission of amendments prior to implementation at the NHS site. It is therefore essential that a review of the NHS R&D SOPs is undertaken for each site. This should be noted during the Sponsor Amendment Approval process and recorded on the Sponsor Amendment Approval – Multi-Site documentation (Appendix E).

All amendments must be sent to the Research Governance Officer for Sponsor review. All documentation to be amended along with relevant amendment forms must be included. The Research Governance Officer or their delegate will review the documentation and will formally confirm that the amendment is 'substantial' and will advise on the approvals required.

The Research Governance Officer or their delegate will review the amendment documentation, and will revise the initial Sponsor Risk Assessment form as necessary. This may require further review by the Research Office if the amendment affects the risk outcome in accordance with SOP -1003 LU Sponsor Risk Assessment.

If an amendment includes the addition of new sites or Third Parties, the relevant SOP -1025 LU Sponsor Approval Process 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 Approval confirmation.

The Research Governance Officer or their delegate will complete the Sponsor Amendment Approval document 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 Officer will confirm to the Chief Investigator the

Sponsor permission to submit the amendment to relevant regulatory authorities.

Sponsor Amendment Approval 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 Approval document (Appendix D) must be retained in the Sponsor file, along with copies of all relevant documentation. A Sponsor Amendment Approval confirmation letter will be sent allowing implementation of the amendment to take place.

3.2 Non-Substantial Amendments

Research not involving Investigational Medicinal Products

Where amendments are deemed to be Non-Substantial/Administrative/Minor as listed in Appendix C, the amendment may be submitted to the REC & NHS Trust R&D offices for Favourable Opinion/ Approval / acknowledgement as necessary ensuring that LU as Sponsor is copied into any correspondence. There is no requirement to complete a specific form when submitting Non Substantial / Administrative / Minor amendments, but it is expected that a brief outline be included in either a covering letter or within the body of the email.

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

4.0 Non- Compliance

Where it is identified that the processes detailed above have not been followed, the SOP -1016 LU Non-Compliance will be implemented at a minimum of a Major finding.

5.0 Responsibilities

Complete Study Risk Assessment Form

	Responsibility	Undertaken by	Activity
1	LU Research Office	Research Governance Officer	Commence completion of Risk Assessment Form
2	LU Research Office	Research Governance Officer	Completion of Sponsor Amendment Approval – First Site & completion of Sponsor Amendment Approval – Multi-Centre.
3	LU Research Office & Chief Investigator	Research Governance Officer & Chief Investigator	Ensure no implementation of amended documentation commences prior to receipt of Sponsor Approval letter.

6.0 Monitoring and Audit Criteria

Key Performance Indicator	Method of Assessment	Frequency	Lead

All research sponsored by LU has appropriate Risk Assessment	Included in the monitoring / audit programme.	Random audits / monitoring conducted on 10% of research activity.	Research Governance Officer

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)**

DISTRIBUTION RECORD:			
Date	**Name**	**Dept**	**Received**

Appendix A - List of amendments requiring MHRA & REC authorisation

Change to the main objective of the trial
Change of the primary or secondary end-points likely to have a significant impact on the safety or scientific value of the trial
Use of a new measurement for the primary end-point
New toxicological or pharmacological data or new interpretation of toxicological or pharmacological data which is likely to impact on the risk-benefit assessment
Addition of a trial arm or placebo group
Significant change of inclusion or exclusion criteria (for example, age range) likely to have a significant impact on the safety or scientific value of the trial
Change of a diagnostic or medical monitoring procedure likely to have significant impact on the safety or scientific value of a trial
Withdrawal of an independent data monitoring committee
Change of investigational medicinal product(s)
Change of dosing/mode of administration of investigational medicinal product(s)
Any other change of trial design likely to have a significant impact on primary or major secondary statistical analysis or on the risk-benefit assessment
Change of the sponsor to sponsor's legal representative
Temporary halt of the trial or temporary halt at a trial site, and re-start of the trial following a temporary halt
Change of the definition of the end if the trial

Appendix B - List of amendments requiring REC Favourable Opinion

Significant changes to information provided to subjects – for example, subject information sheets, consent forms, diaries, letters to GPs or other clinicians, letters to relatives/carers (whether generic to the whole trial or specific to particular trial site
Significant changes to recruitment and consent procedures, including the inclusion of adults lacking capacity in the trial
Significant increase to the radiation exposures to subjects from the protocol
Change of insurance or indemnity arrangements for the trial
Change to the payments, benefits or incentives to be received by subjects or researchers in connection with taking part in the trial, or any other change giving rise to a possible conflict of interest on the part of any investigator/collaborator
Change of the Chief Investigator
Change of Principal Investigator at a trial site
Addition of new trial site not listed with the original request for authorisation and REC application
Change to the definition of a trial site
Any other significant change to the conduct or management of the trial at particular trial sites
Early closure or withdrawal of a site
Any other significant changes to the terms of the REC application

Appendix C–Amendments not normally requiring notification

Changes to the identification of the trial (for example, change of title)
Increase in duration of the trial, provided that the exposure to treatment is not extended, the definition of the end of trial is unchanged and there is no change to monitoring arrangements
Changes to the numbers of subjects planned in the UK as a whole or at individual trial sites, provided that there is no change to the total number of subjects in the trial or the increase/decrease is insignificant in relation to the overall sample size
Change in the documentation used by the research team to record trial data (for example, case report form or data collection form)
Additional safety monitoring which is not part of an urgent safety measure but is taken on a precautionary basis
Changes to the research team other than to the Chief or Principal Investigators
Changes to contact details
Changes to the internal organisation of the sponsor or persons to whom tasks have been delegated
Changes to the logistical arrangements for transporting or storing samples
Changes to technical equipment
Inclusion or withdrawal of another Member State or third country
Minor clarifications to the protocol
Minor clarifications or updates of subjects information documentation
Corrections of typographical errors

Appendix D

Sponsor Amendment Green Light Sign-Off

Study Title (in full):	
Reference No:	
Amendment No:	

	N/A	In Progress	Complete	Date Completed
Risk Assessment	☐	☐	☐	
Risk Mitigation Approved	☐	☐	☐	
Insurance Office Letter Received	☐	☐	☐	
Finance Approval received	☐	☐	☐	
IT Services Approval received	☐	☐	☐	
Monitoring Plan Amended	☐	☐	☐	
MHRA Approval Received	☐	☐	☐	
Ethics Favourable Opinion Received	☐	☐	☐	
R&D Approval Received (first site)	☐	☐	☐	
3rd Party Contracts Fully Executed	☐	☐	☐	
Documents added to Trial Master File	☐	☐	☐	
Pharmacy Amendment Green Light received	☐	☐	☐	
Sponsor Amendment Green Light Letter sent (date)				

Appendix E

Multi Centre Site Sponsor Amendment Green Light Process

Study Title (in full):	
Reference No:	
Amendment No:	

Name of Site:		Name of PI:	
Contact Name for PI:		Contact name R&D:	
Address:		Address R&D:	
Contact No:		Contact No R&D:	

	N/A	Yes	Date
Notified to MHRA	☐	☐	
Notified to Ethics	☐	☐	
R&D Approval	☐	☐	
Contract Fully Executed	☐	☐	
Pharmacy Green Light Given	☐	☐	
Date Sponsor Amendment Green Light Given			