LOUGHBOROUGH UNIVERSITY RESEARCH OFFICE
STANDARD OPERATING PROCEDURE

Loughborough University (LU) Research Office
SOP–1025 LU

Sponsor Approval Process for NHS Research Sponsored by Loughborough University

Effective Date: October 2015

1.0 Introduction

This Standard Operating Procedure (SOP) describes the procedures used by the Research Office within Loughborough University (LU) when completing the Sponsor Approval Process.

The outcome is that the Research Office is able to confirm that LU will act as research Sponsor.

2.0 Scope

This SOP applies to all staff, and any external individual who approach LU to request that the organisation act as Sponsor for research activity that falls under the Research Governance Framework (v2. 2005).

3.0 Sponsor Approval Process

The Sponsor Approval Process includes but is not limited to:

- identifying appropriate actions required to mitigate any identified risks
- receiving confirmation that all necessary approvals and permissions from relevant authorities are in place for each site
- has received satisfactory confirmation that the research can be delivered in accordance with the approved protocol / contracts and study documentation

The process will begin on receipt of a valid Sponsor application to the Research Office via email researchpolicy@lboro.ac.uk. Documents required for an application are listed in SOP-1002 Initial Documentation Review Process.

The Research Office will acknowledge receipt by email and will confirm whether or not the application is deemed valid. If the application is not deemed valid, details of additional documentation required will be requested.

Once a valid application has been confirmed, the Sponsor Approval Process will commence. This begins with implementation of the Risk Assessment SOP-1003 LU.

When completing the Risk Assessment Form included within the Risk Assessment SOP-1003 LU the following documents must be completed (as appropriate) by the Research Governance Officer or their delegate.

- Sponsor Approval – First Site (Appendix A)
- Sponsor Approval – Multi-Site (Appendix B)
- Sponsor Approval – Agreements Listing (Appendix C)

3.1 Sponsor Approval – First Site

This document must be completed for every Sponsor application received by the Research Office. Completion of this document provides assurance that all the relevant documentation has been received to confirm appropriate approvals and permissions, including but not limited to:

- Sponsor Risk Assessment
- Sponsor Indemnity confirmation
- Regulatory Authority approvals
- REC Favourable opinion
- Finance approval
- Third party agreements

Once completed a copy must be retained in the Sponsor file for the study along with documentary evidence. An email confirming Sponsor Approval and therefore giving permission to commence the research will be generated. Recruitment activity must NOT commence prior to receipt of the Sponsor Approval Confirmation email.

3.2 Sponsor Approval – Multi-Site

This document must be completed when it is identified that there is more than a single site involved in delivering the research. Sites are usually NHS organisations but may also be non-NHS organisations that have a duty of care for participants in the research study.

Care must be taken to ensure that the relevant regulatory authorities have been informed of the participation of the sites prior to the Sponsor Approval being confirmed for that site.

Completion of this document may be delegated to the Chief Investigator for a multi-centre study. Once completed a copy must be sent to the Research Office along with all documentary evidence. An email confirming Sponsor Approval and therefore giving permission for each individual site will be generated. Recruitment must NOT commence

prior to receipt of the Sponsor Approval Confirmation email for each individual site.

3.3 Sponsor Approval – Agreements Listing

This document must be completed by the Research Governance Officer or delegate while conducting the Sponsor Risk Assessment. Each participating site and all Third parties involved in the delivery of the research study must be listed.

Two originals of The Roles and Responsibilities of the Chief Investigator agreement will be sent to the Chief Investigator for signature by the Research Office. A fully executed original must be retained in the Sponsor file, and also in the Trial Master File and must be in place prior to Sponsor Approval confirmation.

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 Approval – First Site, appropriate delegation of Sponsor Approval – Multi-Site, and completion of Sponsor Approval – Agreements Listing.
3	LU Research Office & Chief Investigator	Research Governance Officer & Chief Investigator	Ensure no recruitment commences prior to receipt of Sponsor Approval email.

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: 23/10/15**

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

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

APPENDIX A

Sponsor Approval Sign-Off

Study Title (in full):	
Reference 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 Completed	☐	☐	☐	
Initiation Visit Completed	☐	☐	☐	
Ethics Favourable Opinion Received	☐	☐	☐	
R&D Approval Received (first site)	☐	☐	☐	
3rd Party Contracts Fully Executed	☐	☐	☐	
Trial Master File Set-Up	☐	☐	☐	
Pharmacy Approval received	☐	☐	☐	
Sponsor Approval Email sent (date)				

APPENDIX B

Multi Centre Site Sponsor Approval Process

Study Title (in full):	
Reference 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 Ethics	☐	☐	
R&D Approval	☐	☐	
Contract Fully Executed	☐	☐	
Site Initiation Completed	☐	☐	
Pharmacy Approval Given	☐	☐	
Date Sponsor Approval Given			

Duplicate page as required for each site

APPENDIX C

List of 3rd Party Contracts / Site Agreements Required

Study Title (in full):	
Sponsor Ref. No:	

Mandatory

Roles & Responsibilities of Chief Investigator:		
Name of Chief Investigator:		
Name of Sponsor:		
Two Fully Signed & Executed Originals received. (One sent to CI. One kept in Sponsor File)		☐

Required

Name of Vendor:	
Contact Name:	
Address:	
Contact No:	
Email:	

	Yes	**Date**
Negotiation Started	☐	
Negotiation Complete	☐	
Fully Executed Contract Received	☐	

(Duplicate table as required for each Vendor / Site)