



**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-1025 UoL**

Version 3, October 2016

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

OFFICE BASE

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Effective Date: April 2017

## 1.0 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.

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

## 2.0 Scope

This SOP applies to all staff, and any external individual who approach the UoL to request that the organisation act as Sponsor for research activity.

## 3.0 Sponsor Green Light Process

The Sponsor Green Light 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 Governance Office via email [uolsponsor@le.ac.uk](mailto:uolsponsor@le.ac.uk) Documents required for an application are listed on the Sponsor Green Light Review Process Flowchart ([Appendix 1](#)).

The Research Governance 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 Green Light Process will commence. This begins with implementation of the [Risk Assessment SOP S-1003 UoL](#).

When completing the Risk Assessment Form or Sponsor review documents included within the [Risk Assessment SOP S-1003 UoL](#) the following documents must be completed (as appropriate) by the Research Governance Manager or their delegate and filed in sponsor files.

- Sponsor Green Light – First Site ([Appendix 2](#))
- Sponsor Green Light – Multi-Site ([Appendix 3](#))
- Sponsor Green Light – Agreements Listing ([Appendix 4](#))

### **3.1 Sponsor Green Light – First Site**

This document or relevant entities/workflows in the EDGE system, must be completed for every Sponsor application received by the Research Governance Office. Completion 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
- HRA approval
- Finance approval
- Third party agreements

An email/ letter confirming Sponsor Green Light and therefore giving permission to commence the research will be generated. Recruitment activity must NOT commence prior to receipt of the Sponsor Green Light Confirmation email/ letter.

### **3.2 Sponsor Green Light – Multi-Site**

This document or relevant entities/workflows in the EDGE system, 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 Green Light being confirmed for that site.

Completion of this document or relevant entities/workflows in the EDGE system, may be delegated to the Chief Investigator for a multi-centre study. Once completed a copy must be sent to the Research Governance Office along with all documentary evidence. An email/ letter confirming Sponsor Green Light and therefore giving permission for each individual site will be generated. Recruitment must NOT commence prior to receipt of the Sponsor Green Light Confirmation email/ letter for each individual site.

### **3.3 Sponsor Green Light – Agreements Listing**

This document or relevant entities/workflows in the EDGE system, must be completed by the Research Governance Manager or delegate while conducting the Sponsor Risk Assessment and Sponsor review documentation. Each participating site and all third parties involved in the delivery of the research study must be listed.

The completed document must be sent to the relevant departments for further action as detailed in [SOP S-1005 UoL Contracts / Third Party Agreements](#).

Two originals of The Roles and Responsibilities of the Chief Investigator agreement will be sent by the Research Governance Office to the Chief Investigator for signature. 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 Green Light confirmation.

## **4.0 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.

## 5.0 Responsibilities

### Complete Study Risk Assessment Form


Responsibility	Undertaken by	Activity
1 Sponsor	Research Governance Manager or their delegate	Commence completion of Risk Assessment Form and Sponsor review documentation.
2 Sponsor	Research Governance Manager or their delegate	Completion of Sponsor Green Light – First Site, appropriate delegation of Sponsor Green Light – Multi-Site, and completion of Sponsor Green Light – Agreements Listing.
3 Sponsor & Chief Investigator	Research Governance Manager or their delegate & Chief Investigator	Ensure no recruitment commences prior to receipt of Sponsor Green Light letter.

## 6.0 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

## 7.0 Development and approval Record for this document

<b>Author/Lead Officer:</b>	Wendy Gamble
<b>Job Title:</b>	Research Governance Manager
<b>Reviewed by:</b>	Research Sponsorship Management and Operations Group
<b>Approved by:</b>	Professor Nigel Brunskill 
<b>Date Approved:</b>	10/04/2017

## 8.0 Review Record

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
April 2015	2	UoL RSMOG	SOP reviewed and revised. Incorporated minor changes to text, numbering appendices (instead of A,B,C and D) in line with other SOPs. Changed Appendix 1 from Sponsorship application form to Sponsor flowchart. Minor administrative changes to dates and inclusion of a footer. Addition of Loughborough University to front page
Oct 2016	3	Diane Delahooke	Logo changed. Made consistent with UHL SOP. Green light checklist updated.

## 9.0 Distribution Record

Date	Name	Department	Received