



**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-1025 UoL**

Version 4.0, September 2021

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

OFFICE BASE

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

Effective Date: October 2021

## **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 [rgosponsor@le.ac.uk](mailto:rgosponsor@le.ac.uk). Documents required for an application are listed on the Research Governance webpages and in addition, Appendix 2.

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 Site Sponsor Green Light Checklist (Appendix 2) must be completed (as appropriate) by the Sponsor representative and retained in the Sponsor files

## **4.0 Site Sponsor Green Light Checklist**

This document 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
- Site approval (i.e., Confirmation of Capacity and Capability, or organizational equivalent)
- Third party agreements

**An email confirming Sponsor Green Light and therefore giving permission to commence the research will be issued per site. Recruitment activity must NOT commence prior to receipt of the Sponsor Green Light email.**

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.

## 5.0 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.

## 6.0 Responsibilities

### Complete Study Risk Assessment Form


	Responsibility	Undertaken by	Activity
1	Sponsor	Sponsor delegate	Commence completion of Risk Assessment Form and Sponsor review documentation.
2	Sponsor	Sponsor delegate	Completion of Site Sponsor Green Light Checklist and issuing of Sponsor Green Light email.
3	Sponsor & Chief Investigator, or Principal Investigator, or their delegates	Sponsor delegate & Chief Investigator, or Principal Investigator, or delegates	Ensure no recruitment commences prior to receipt of Sponsor Green Light email.

## 7.0 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

### 8.0 Development and approval Record for this document

<b>Author/Lead Officer:</b>	Cat Taylor
<b>Job Title:</b>	Head of Research Assurance
<b>Reviewed by:</b>	Research Sponsorship Management and Operations Group
<b>Approved by:</b>	Professor Nigel Brunskill 
<b>Date Approved:</b>	13/10/2021

### 9.0 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.
Sept 2021	4.0	Cat Taylor	Revision to the information regarding the Sponsor Green Light process. Removal of Appendices 3-4 (marked as obsolete). Reformatting of Appendix 2 to be one Site Sponsor Green Light Checklist for all studies.

### 10.0 Distribution Record

Date	Name	Department	Received