

**UNIVERSITY OF LEICESTER
&
UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST**

JOINT RESEARCH SUPPORT OFFICE

STANDARD OPERATING PROCEDURES

**UHL Research Support Office
SOP S-1014 UHL 12 March 2020**

**Standard Operating Procedure for Green Light Process for Research
sponsored by
University Hospitals of Leicester NHS Trust (UHL)**

PGC Registration – C17/2014

OFFICE BASE

Research & Innovation
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1. Introduction

This Standard Operating Procedure (SOP) describes the procedures used by the University Hospitals of Leicester NHS Trust (UHL) when completing the Sponsor Green Light Process.

The outcome is that the UHL is able to confirm that the Organisation will act as research Sponsor.

2. Scope

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

3. 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 via email to UHLsponsor@uhl-tr.nhs.uk. Documents required for an application are listed on the Sponsor Application Form Appendix 1 of SOP S-1002 UHL

The UHL 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 a Sponsor Review and where required in accordance with SOP S-1003 UHL a Risk Assessment.

Once the Sponsor review and where appropriate Risk Assessment have been completed, all relevant attribute lists and workflows within the EDGE system have been confirmed as complete an email to give authorisation to submit to the Health Research Authority (HRA) and other regulatory bodies (as appropriate) will be sent from the UHLsponsor@uhl-tr.nhs.uk email.

3.1 Sponsor Green Light – UHL as a site (Single or Multi-centre studies)

Once authorisation to submit to relevant approval bodies has been given, the study will be passed to the Support Officer (SO). The SO will assist the Chief Investigator with submission, and will process the study for UHL confirmation of capacity and capability.

Confirmation of Green Light will be given at the same time as confirmation of Capacity and Capability. The confirmation will be by email from the email box of

an authorised member of the R&I Team when all relevant attributes and Workflows have been completed. A list of all workflows required for UHL Sponsored studies can be found in the General Documents area of the EDGE database entitled '**Working Instructions for EDGE UHL SPONSOR Attributes & Workflows**'

Individuals with appropriate authorisation are:

- Director of R&I
- Associate director of R&I
- Deputy Director of R&I
- Head of Research Operations
- R&I Manager

3.2 Sponsor Green Light – Multi-centre (Sites outside UHL)

Each site will be added to the EDGE system. All relevant attribute lists and Workflows will be added to the site instance and be fully completed before Sponsor Green Light is confirmed for each site. A list of required attribute Lists and Workflows named '**Working Instructions for Attributes and Workflows for Multi-Site Management of UHL Sponsored studies**' can be found in General Documents within the EDGE system.

Once the authorised individual (as in 3.1) for UHL as Sponsor is satisfied that all workflows are ticked 'green' and all Attributes are complete a confirmation email may be sent to the Chief Investigator to confirm Green light for a specific site. Where study management is different to the CI the email will be copied as appropriate. It may be appropriate to ensure that the site is also copied into the email, but this will be on a study by study basis and will depend entirely on the agreements in place for the management of the multi-centre study.

4. Non- Compliance

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

5. Responsibilities

	Responsibility	Undertaken by	Activity
1	Sponsor	Head of Research Operations or delegate	Commence completion of all relevant EDGE attributes Lists and Workflows
2	Sponsor	Head of Research Operations or delegate	Send confirmation of Green light
3	Sponsor & Chief Investigator	Head of Research Operations or delegate & Chief Investigator	Ensure no recruitment commences prior to receipt of Sponsor Green Light letter.

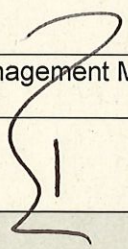
6. Monitoring and Audit Criteria

Key Performance Indicator	Method of Assessment	Frequency	Lead
All research sponsored by UHL has appropriate Risk Assessment	Included in the monitoring / audit programme.	Random audits / monitoring conducted on a risk based assessment of research activity.	Head of Research Operations

7. Legal Liability Statement

Guidelines or Procedures issued and approved by the Trust are considered to represent best practice. Staff may only exceptionally depart from any relevant Trust guidelines or Procedures and always only providing that such departure is confined to the specific needs of individual circumstances. In healthcare delivery such departure shall only be undertaken where, in the judgement of the responsible healthcare professional it is fully appropriate and justifiable – such a decision to be fully recorded in the patient's notes and in the research site file.

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:	Carolyn Maloney		Job Title: Head of Research Operations
Reviewed by:	UHL R&I Management Meeting		
Approved by:			11/06/2020
REVIEW RECORD			
Date	Issue Number	Reviewed By	Description Of Changes (If Any)
March 2015	2	R&I Management Committee	Logo changes and changes to R&I Office name
October 2015	3, 4 & 5	Carolyn Maloney	Version of SOP to correlate with appendices
July 2016	7	CM, LW, JJ	Consistency checks.
February 2017	9	Carolyn Maloney	Logo changes
March 2018	10	CM	Change in sponsor green light process to reflect use of EDGE and Multi-centre study management in EDGE
September 2018	11	CCL	Updated R&I logo
March 2020	12	CM/LW	Revision of wording and removal of Loughborough university
DISTRIBUTION RECORD:			
Date	Name	Dept	Received