University of Leicester Research Governance Office

Standard Operating Procedures

SOP S-1025 UoL

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

Version 5.0, March 2024

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Effective Date: April 2024

This SOP will be implemented in line with this document's effective date for all UoL Sponsored research still in set up. For active clinical research that is already in the recruitment phase (or further) at the time of implementation, this SOP must be implemented within 3 months of the effective date.

Please note the appendices associated with this SOP may be subject to interim changes. Please ensure that appendices are downloaded from the RGO webpages prior to use to ensure the latest version of the document is being used.

1.0 Introduction

This Standard Operating Procedure (SOP) describes the procedures used by the Research Governance Office (RGO) when completing the Sponsor Green Light Process for research Sponsored by the University of Leicester (UoL). The Sponsor must have a robust Sponsor Green Light Process which confirms that all necessary reviews and approvals have been completed before a study opens, with commensurate processes in place for the review and approval of amendments.

The outcome is that the RGO is able to confirm that the UoL will act as research Sponsor.

2.0 Definitions

Release process for IMPs (CTIMPs only): The release process for Investigational Medicinal Products (IMPs) differs from that for authorised medicinal products as it requires both technical and regulatory approval. These can often be referred to as technical and regulatory release.

- **Technical release:** This involves the Sponsor of a trial ensuing that a Qualified Person (QP) certifies that IMP has been manufactured to European Union (EU) Good Manufacturing Practice (GMP) and the Clinical Trials Authorisation (CTA).
- **Regulatory release:** This involves the Sponsor ensuring that competent authority approval, REC favourable opinion and HRA approval has been received.

Sponsor Green Light: The Sponsor is responsible for giving the 'go ahead' for the initial opening of a study/trial (both study-wide and at each site involved) and for any amendment (if relevant). This is known as Sponsor Green Light. The Sponsor must have a documented process for ensuring that all steps have been completed prior to granting Sponsor Green Light.

3.0 Sponsor Green Light Process

The Sponsor Green Light (SGL) process will commence upon receipt of a valid Sponsor Application and includes, but is not limited to:

1. A review of the application and associated documents by the RGO (refer to SOP S-1002 for further details)
2. Identifying appropriate actions required to mitigate any identified risks (refer to SOP S-1003 for further details)
3. Receiving confirmation that all necessary approvals and permissions from relevant authorities are in place for the study as a whole
4. Receiving confirmation that all necessary approvals and permissions from relevant third parties are in place
5. Receiving confirmation that the research can be delivered in accordance with the approved protocol/contracts and study documentation at each site (refer to SOP S-1006 for further details)
6. Completion of a SGL checklist*
7. Issue of Sponsor Green Light

*Completion of the SGL checklist provides assurance that all the relevant documentation has been received to confirm appropriate approvals and permissions are in place. The checklist includes, but is not limited to the confirmation of:

- Sponsor Risk Assessment completion (if relevant)
- Sponsor Indemnity
- Chief Investigator (CI) acceptance of the agreed CI Roles and Responsibilities**
- Regulatory approval (i.e MHRA approval, HRA approval and REC Favourable opinion etc)
- Site approval (i.e., Confirmation of Capacity and Capability, or organisational equivalent and relevant agreements)
- Finance approval/confirmation of funding
- Third party agreements
- Data Risk Assessment (DRA) (where available), Record of Processing Activities (ROPA), Data Protection Impact Assessment (DPIA) (where applicable)

**The CI Roles and Responsibilities will be sent by the RGO to the CI for review and signed agreement. A fully executed copy must be retained in the Sponsor file and Trial Master File (refer to SOP S-1010 for further details).

Only once all appropriate reviews have been undertaken and all relevant approvals/permissions/agreements are in place will Sponsor Green Light be issued. The CI must ensure that research is not implemented at a site prior to Sponsor Green Light.

3.1 The SGL process for applications submitted via email

1. Once all the necessary documents have been received the CI (or delegate) must ensure that rgosponsor@le.ac.uk are sent copies of relevant research approvals/permissions/agreements.
2. Following the receipt of HRA approval, the RGO will issue a 'Next Steps' email. This will detail any outstanding actions required for SGL. Confirmation will also be requested that approval documents have been carefully checked and list all the required research documentation.
3. Once all outstanding actions have been undertaken, the RGO will complete a SGL checklist.
4. An email confirming Sponsor Green Light and therefore granting permission to commence the research will be issued per site. A copy of this email must be retained in the Trial Master File and Investigator Site File as applicable. Recruitment activity at a site must not commence prior to receipt of the Sponsor Green Light email.

On occasion, sites may request confirmation of the technical release of an IMP prior to granting Confirmation of Capacity and Capability. Where this cannot be handled via the above referenced process, and only in exceptional circumstances, separate Sponsor confirmation will be sent via email.

Note;

If a study involves multiple work packages where the completion of one package informs the implementation of another, where this is not subject to the amendment process, Sponsor Green Light will be issued per work package, per site.

3.2 The SGL process for applications submitted via Infonetica

1. Once all the necessary documents have been received the CI (or delegate) must ensure that copies of all relevant research approvals/permissions/agreements are uploaded to Infonetica.
2. The CI (or delegate) must create the relevant Sponsor Green Light request form within Infonetica.

Note: There are two different Sponsor Green Light request forms;

- First Site
- Subsequent Sites (for multicentre studies)

3. The RGO will review the request and will grant Sponsor Green Light for the research to start at the first site via Infonetica.
4. For additional sites, the CI (or delegate) must complete the 'subsequent site' Sponsor Green Light request form per site. The RGO will review each request and will grant Sponsor Green Light per site via Infonetica.

On occasion, sites may request confirmation of the technical release of an IMP prior to granting Confirmation of Capacity and Capability. Where this cannot be handled via the above referenced process, and only in exceptional circumstances, separate Sponsor confirmation will be sent via email.

For studies involving multiple work packages where the completion of one work package informs the implementation of the next, where this is not subject to the amendment process, the opening of subsequent work packages will be handled via the subsequent site Sponsor Green Light Process within Infonetica.

4.0 Non-Compliance

Where it is identified that the processes detailed above have not been followed, this will initially be raised with the CI (or their delegate). If required this may trigger the need for a Corrective Action/Preventative Action (CAPA) document to be instigated (refer to SOP S-1012 for further details). Where non-compliance persists, SOP S-1016 UoL' Non-Compliance' will be implemented at a minimum of a Major finding.

5.0 Responsibilities

Responsibility	Undertaken by	Activity
CI	CI (or delegate)	Submit application for RGO review
Sponsor	Sponsor (or Delegate)	Review application and undertake Risk Assessment (where applicable)
CI	CI (or delegate)	Ensure all relevant approvals/permissions and agreements are received and copies are provided to the RGO.

Responsibility	Undertaken by	Activity
Sponsor / CI	Sponsor (or delegate)/ CI (or delegate)	For applications handled outside of Infonetica; RGO to complete Sponsor Green Light Checklist and issue Sponsor Green Light via email. For applications handles within Infonetica; CI to complete relevant Sponsor Green Light request form. RGO to review and issue Sponsor Green Light via Infonetica.
Sponsor/ CI/ Principal Investigator, or their delegates	Sponsor/ CI/ Principal Investigator, or their delegates	Ensure no recruitment commences prior to receipt of Sponsor Green Light.

6.0 Development and approval Record for this document

Author	Job title	Reviewed by	Approved by	Date approved
Cat Taylor	Head of Research Governance	UoL Research Sponsorship Management and Operation Group (RSMOG)	Professor Nigel Brunskill 	25/03/2024

7.0 Review Record

This table is used to track the changes made on revised/reviewed versions.

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
April 2015	**2.0**	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	3.0	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.
March 2024	5.0	Cat Taylor	Major updates to wording to clarify the Sponsor Green Light process following the introduction of Infonetica. Administrative changes

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
			Revision of Roles and Responsibilities table to reflect updates Revision of Information relating to non-compliance Removal of monitoring and audit criteria and distribution record.