Research Governance Office Sponsorship Standard Operating Procedures

Sponsor Green Light

SOP Reference	S-1025
Version and Date	V6.0 April 2026
Author	
Name	**Claire Fitzpatrick**
Job Title	**Research Quality Assurance Officer**
Reviewer/Approver	
Name	**Dr Cat Taylor**
Job Title	**Head of Research Governance**
Signature	
Date	**28 April 2026**
Effective Date*	28 April 2026
Next Review Date	April 2029

1.0 Introduction and Scope

The Sponsor must have a documented process for ensuring that all necessary reviews and approvals are complete before a trial begins. The University of Leicester (UoL) utilises the Sponsor Green Light (SGL) process to achieve this obligation. This Standard Operating Procedure (SOP) describes the procedures to be followed by researchers and the Research Governance Office (RGO) when completing the SGL process and it applies to all research studies (referred to as 'trials' hereafter) sponsored by UoL.

2.0 Sponsor Green Light Process

The process of gathering the necessary documentation will begin during the Initial Sponsor Review (refer to SOP S-1002) and will end upon completion of the relevant SGL request and approval process as outlined below.

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 commenced at a site prior to Sponsor Green Light.

2.1 SGL Process for pre-Infonetica Trials

1. CI (or delegate) sends copies of approvals/permissions/agreements to rgosponsor@le.ac.uk.
2. Following the receipt of HRA approval, the RGO issues a 'Next Steps' email detailing any outstanding actions. Confirmation will also be requested that approval documents have been carefully checked and list all the required research documentation.
3. RGO completes SGL checks once the research team confirms all actions are completed.
4. RGO issues an email confirming Sponsor Green Light, granting permission to commence the trial at a site. A copy of this email must be retained in the Trial Master File and Investigator Site File as applicable. Recruitment activity must not commence prior to receipt of the site-specific Sponsor Green Light email.

Note: Where a study involves multiple work packages, that aren't subject to the modification process, SGL will be issued per work package, per site. The work package details should be clearly specified in the SGL request form.

2.2 SGL Process for Infonetica Trials

1. CI (or delegate) creates the relevant Sponsor Green Light request form.
2. CI (or delegate) uploads approvals/permissions/agreements as requested within Infonetica.
3. RGO reviews the request and, upon receipt of the relevant information, grants SGL.
4. For multi-centre trials, the CI (or delegate) must request SGL for each site individually.
5. The RGO will review each request and will grant SGL per site.

Note: Where a study involves multiple work packages, that aren't subject to the modification process, SGL will be issued per work package, per site. The work package details should be clearly specified in the SGL request form.

3.0 Technical Release of IMP (CTIMPs only)

The release of an IMP for use in a CTIMP requires both technical and regulatory approval.

- **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 have been received.

The provision of SGL to a site is contingent upon confirmation that the IMP has been received at the site. Where a site requires confirmation of technical release of the IMP prior to granting Confirmation of Capacity and Capability, the Sponsor may, in exceptional circumstances, provide separate confirmation of technical release via email. Confirmation of technical release does not constitute SGL. SGL will only be issued to a site once both technical and regulatory release requirements have been met and IMP receipt at site has been confirmed.

4.0 Non-Compliance

If processes are not followed, this will initially be raised with the CI (or their delegate). If required this may trigger the need for a Corrective and Preventative Action (CAPA) document to be instigated.

5.0 Development Record

The table below summarises the revisions introduced in this version. Full historical change records are available within archived SOP versions.

Date	Version number	Description of changes
April 2026	6.0	• Streamlining of document to avoid repetition and aid understanding. • Removal of responsibilities table as responsibilities are laid out within the body of the SOP. • Removal of full historical SOP review record; only the latest approved revision is now displayed, with prior versions retained in the document archive. • Removal of Appendix 2 – Site SGL Checklist. This will now become an internal working document.