



**University of Leicester and University Hospitals of Leicester  
NHS Trust joint Research Support Office Standard Operating  
Procedures**

**University of Leicester (UoL) Research Governance Office**

**SOP S-1047 UoL**

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

Office Base

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**Version 1.0, May 2023**

**Effective Date: May 2023**

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 procedure to ensure that all regulatory and Sponsor processes have been completed and to therefore confirm the end of Sponsor Green Light.

Once a study/trial has completed all activity, there are a number of tasks that must be undertaken as part of regulatory/statutory requirements. The University of Leicester (UoL), as Sponsor, is required to ensure that the Chief Investigator (CI) carries out all tasks within 12 months of the declared end of study date.

## 2.0 Scope

This SOP applies to all research sponsored by the UoL.

## 3.0 Outcome

The outcome of following this SOP will be that UoL, as Sponsor, can be assured that all relevant processes and regulatory/statutory requirements have been successfully completed prior to archiving a study/trial.

## 4.0 Procedure

The 12 months to complete the End of Sponsor Green Light Process will commence at the 'end of study' date as written/recorded on the relevant End of Study Declaration Form. This date will be added to the Sponsor database and will be considered as the start of the 12 month timeframe.

1. Upon receipt of the End of Study Declaration Form, the Research Governance Office will send;
  - an acknowledgement of End of Study and the 'End of Sponsor Green Light Process' checklist (Appendix 1) to the CI (or their delegate) detailing the required activities to be completed
  - an email reminder notification at 6 months
  - an email reminder notification at 11 months
  - an email reminder(s) notification at regular intervals post-12 months where a completed form has not been submitted.

It is expected that researchers **complete all the tasks listed in the checklist in full** prior to submitting the form back to the Research Governance Office.

Incomplete forms, and/or forms that have incomplete tasks listed on them will not be accepted. The Research Governance Office will confirm that **all tasks must be completed in full** before the End of Sponsor Green Light Process can be concluded.

2. Where it is anticipated that tasks will not be completed within the 12 month timeframe, the researcher must contact the Research Governance Office. Email reminders will be issued at regular intervals until a complete checklist can be submitted.

3. Completed End of Sponsor Green Light Process checklists (Appendix 1) must be submitted to the Research Governance Office, [rgosponsor@le.ac.uk](mailto:rgosponsor@le.ac.uk).
4. The Research Governance Office will acknowledge receipt of the checklist via email and confirm that the End of Sponsor Green Light Process has been completed.
5. A copy of the above must be filed in the Trial Master File/Investigator Site File.
6. The Sponsor database will be updated to reflect the end of Sponsorship.
7. The Sponsor file for the study/trial will be archived.


## 5.0 Non-Compliance

In cases where there has been no response, or there is a failure to demonstrate compliance with this SOP, this will be discussed with the Head of Research Governance and a resolution may be sought in line with the Non-Compliance SOP S-1016, and the decision to sponsor future research may be affected.

## 6.0 Responsibilities

Responsibility	Undertaken by	Activity
CI	CI or delegate	Complete End of Sponsor Green Light Process Checklist.
Sponsor	Sponsor	Remind CI of requirement.
Sponsor	Sponsor	Maintain and update Sponsor files and database following the completion of the End of Sponsor Green Light Checklist.

## 7.0 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 	18/05/2023

## 8.0 Review Record

This table is used to track the development and approval of the document and any changes made on revised/reviewed versions:

Date	Issue Number	Reviewed By	Description Of Changes (If Any)