UNIVERSITY OF LEICESTER
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JOINT RESEARCH & DEVELOPMENT SUPPORT OFFICE

STANDARD OPERATING PROCEDURES

University of Leicester (UoL) Research Governance Office
SOP S-1026 UoL

Version 4.0, September 2021

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

OFFICE BASE

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Effective Date: October 2021

1. INTRODUCTION

This Standard Operating Procedure (SOP) describes the procedures used by the Research Governance Office within the University of Leicester (UoL) when completing the Sponsor Green Light (SGL) process for amendments to research that has previously received formal approval.

The outcome is that the Research Governance Office is able to confirm that the UoL has conducted a Sponsor review of the proposed amendment, and where applicable, have undertaken and revised the Risk Assessment and is able to continue to act as research Sponsor.

2. SCOPE

This SOP applies to all research where the UoL acts as Sponsor.

3. CATEGORIES OF AMENDMENTS

Amendments are viewed as changes to any research documentation that has previously been reviewed and approved by regulatory authorities and the Sponsor.

There are essentially two amendment types:

- Substantial amendments
- Non-Substantial amendments

It is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial. Therefore, you must seek advice and approval from the Sponsor prior to the submission and/or implementation of any amendment to your study. The only exception is the requirement to implement an Urgent Safety Measure which is discussed in detail in SOP S-1029.

3.1 Substantial amendment

A substantial amendment is a change that is likely to have a significant impact on:

- The safety, or physical or mental integrity of the trial subjects
- The scientific value of the study
- The conduct or management of the study
- The quality or safety of the Investigational Medicinal Product

Examples of Substantial Amendments can be found on the HRA website.

3.2 Non-Substantial Amendments

Examples of Non-Substantial Amendments can be found on the HRA website.

4. PROCESS FOR ALL AMENDMENT TYPES

As of June 2020, the amendment process has changed. Researchers must complete the **amendment tool** and utilise the **online submission portal** – details are described in full on the HRA website and the IRAS help sections on amending your approvals:

- HRA: https://www.hra.nhs.uk/approvals-amendments/amending-approval/
- IRAS help: https://www.myresearchproject.org.uk/help/hlpamendmentsresearch.aspx

Please refer to Appendix 7 "How to Submit an Amendment Instruction Sheet" for full guidance on how to prepare and submit an amendment.

All amendments must be sent to the Research Governance Office for Sponsor review. The Chief Investigator (or their delegate) must send all documentation to be amended along with relevant amendment forms, evidence of funding and any other document(s) requested by the Sponsor in order for the amendment to be regarded as valid. The Sponsor will review the documentation and request relevant changes before confirming that the amendment can be submitted for regulatory review.

This process may take up to 14 calendar days.

Where applicable, the study Risk Assessment and Monitoring Plan may be updated. Where additional risk(s) are identified, relevant action must be taken to mitigate such risk(s). This may require further review by the Research Sponsorship Management & Operations Group (RSMOG) or the Research Sponsorship Committee (RSC) if the amendment affects the risk outcome in accordance with SOP S-1003 UoL Sponsor Risk Assessment.

If an amendment includes the addition of new sites or Third Parties, the relevant SOP S-1025 UoL Sponsor Green Light Process and / or SOP S-1005 UoL Contracts will be implemented.

If necessary, a face-to-face meeting with the Chief Investigator and / or study personnel will be requested to discuss the proposed amendment in detail prior to Sponsor confirmation that the amendment can be submitted for regulatory approvals.

Sponsor Green Light (or, where applicable, Sponsor acknowledgment) for the amendment will be confirmed on receipt of documentary evidence that the relevant permissions, any additional contracts or agreements are in place, confirmation of indemnity and regulatory authority approvals have been received. The Amendment Sponsor Green Light Checklist (Appendix 6) and Sponsor Green Light email must be retained in the Trial Master File/Investigator Site File, along with copies of all relevant documentation.

Sponsor Green Light/Acknowledgement will be issued for all amendments and must be received prior to the implementation of any amendment. For multi-site studies, Sponsor Green Light will be issued per site.

It is important to remember that the Sponsor must be sent a copy of any revised study documentation and details of changes in key personnel during the lifecycle of the study.

5. 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. RESPONSIBILITIES

Complete Study Risk Assessment Form

	Responsibility Undertaken by		Activity
	Chief Investigator or their delegate	Chief Investigator or their delegate	Submit all documentation relating to the amendment to the Sponsor rgosponsor@le.ac.uk.
	Sponsor	Head of Research Assurance or delegate	Complete Sponsor review of the proposed amendment, and where applicable, amend the study Risk Assessment and/or Monitoring Plan.
	Sponsor	Head of Research Assurance or delegate	Complete and issue the Amendment Sponsor Green Light Checklist and Sponsor Green Light/Sponsor Acknowledgement of Amendment email.
	Sponsor, Chief Investigator or their delegate, Principal Investigator or their delegate	Head of Research Assurance or their delegate & Chief Investigator or their delegate, Principal Investigator or their delegate	Ensure no implementation of amended documentation commences prior to receipt of Sponsor Green Light/Sponsor Acknowledgement email.

7. 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

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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:	**Cat Taylor**
Job Title:	Head of Research Assurance
Reviewed by:	Research Sponsorship Management and Operations Group
Approved by:	Professor Nigel Brunskill 
Date Approved:	13/10/2021

Review Record

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
April 2015	2	UoL RSMOG	Minor administrative changes to logos and text, date and version changes to footer. Addition of Loughborough University to front page.
Oct 2016	3	Diane Delahooke	Change of logo and made consistent with UHL, references to HRA and EDGE added.
Sept 2021	4.0	Cat Taylor	Revision to the amendment process following the introduction of the Amendment Tool and online submission process. Removal of Appendices 1-5 (marked as obsolete). Reformatting of Appendix 6 to be one Amendment Sponsor Green Light Checklist for all amendment types and all sites. Addition of Appendix 7.

Distribution Record

Date	Name	Department	Received