University of Leicester (UoL) Research Governance Office

Standard Operating Procedures

SOP S-1002 UoL

Sponsor Review Process for Research Sponsored by University of Leicester

Version 6.0 January 2024

Office Base
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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) within the University of Leicester (UoL) when completing a Sponsor review prior to confirming that the UoL will act as the Sponsoring Organisation of a research study.

The review will ensure that:

- All mandatory documentation has been completed to the applicable ethical and quality standards
- The UoL is able to deliver the study with or without external support
- An appropriate Peer/Scientific Review has been conducted
- The study has adequate funding

The outcome is that UoL is assured that it can meet all of its legal and ethical obligations as a Sponsor, and has confirmed that there are robust research documentation and management processes in place to produce a research study of a high standard, and that the rights, safety and wellbeing of research participants are protected.

2.0 Scope

This SOP applies to substantively employed UoL staff and students. Where the research activity is student research, the main supervisor must be a substantively employed UoL staff member.

3.0 Process

3.1 Applying for Sponsorship

An application for Sponsorship, alongside supporting documents, must be submitted through the online portal 'Infonetica' when requesting the UoL act as the Sponsor for a research study. The application form, which is accessed via Infonetica, requests all the necessary information that the RGO require to; conduct a thorough Sponsor Review, to inform the Sponsor Review Checklist and/or the Sponsor Risk Assessment (where one is required, see SOP S-1003) and complete the Sponsor Green Light Process (SOP S-1025). Guidance videos on how to use Infonetica are accessible via the RGO webpages (UoL login required).

The supporting documents will vary depending on the study type, the type and number of sites involved, the type and number of participants to be recruited and the funding arrangements. The application form will provide guidance on the documents required depending on your study type.

For HRA/REC purposes all documents must include: **IRAS number, EudraCT number (for CTIMP only), short study title, document title, version number and date, and page numbers (x of y format)**.

i.e., **(IRAS No.)_Short Study Title_Document title_vx.x_DD/MM/YYYY**

We recommend placing these in the footer of your document so they repeat across all pages.

We recommend that all documents be named as **Sponsor Reference Number_Document title_vx.x_DD/MM/YYYY** so that they can be easily identified.

Documents should be submitted for Sponsor Review as version 0.1(v0.1), the completion of the Sponsor Review process will result in final v1.0 documents ready for submission for regulatory approvals.

3.2 Supporting Documents

3.2.1 Protocol

The protocol should detail every aspect of the proposed research and should be regarded as the 'study manual'. Protocol templates available from the RGO webpages (UoL login required) must be used to develop the study protocol. Further guidance on protocol development is available within SOP S-1027.

Failure to use the templates (current versions available here) and/or follow the guidance may invalidate your Sponsor application, and it will be returned to you.

3.2.2 Participant Facing Documentation

Where research involves human participants, participant facing documents such as Participant Information Sheets (PIS) and Informed Consent Forms (ICF) may need to be created.

The RGO has created some template documents which must be used when developing the documents for your study. These are updated regularly and include mandatory wording and content required for regulatory approval. **Failure to use the templates (current versions available here) and/or follow the guidance may invalidate your Sponsor application, and it will be returned to you.**

3.2.3 Study Recruitment Documents

Any posters, adverts, social media posts, videos (or video transcripts) or literature that will be used to raise awareness of a research study must be submitted as part of the Sponsor application and approved prior to use.

3.2.4 Data Flow Diagram

A data flow diagram must be provided. To create a data flow diagram, please refer to the MRCs Data Toolkit Data Flow Diagram.

3.2.5 Full Dataset IRAS

The information in the IRAS form must be consistent with the Protocol and all other study documentation. Every question must be answered in full and references such as 'see above' must be avoided because the form adds and removes questions based on previous answers, and is split into independent sections when it is sent to the various regulatory agencies for review.

Useful pointers:

- Answers must be provided in lay language
- Sections must not be copied and pasted from the protocol
- The 'Frequently Asked Questions' and 'Question Specific Advice' available within IRAS must be referred to.
- The UoL requires a standardised answer to various questions. The standardised wording and information about these can be found on the 'Completing IRAS' page on the RGO website.

3.2.6 SoE/SoECAT

A Schedule of Events (SoE) or Schedule of Events Cost Attribution Tool (SoECAT) should be created for each site type involved in a research study. I.e if sites are doing different activities, then a different SoE or SoECAT will be required for each site. These documents help to ensure that the appropriate resources are identified to support study delivery at a site and that there is clarity for participating organisations about how the costs associated with participating in a study are attributed. A validated SoECAT must be submitted with your Sponsor Application Form. The lead CRN must be contacted and a request made for an Attributing the costs of health and social care research and development (AcoRD) specialist to validate the SoECAT(s). Please allow extra time for the validation process.

3.2.7 Peer Review

All research protocols require appropriate Peer Review (also referred to as "scientific quality review", "independent scientific review" or "independent review"). It is one of the responsibilities of a "Research Sponsor" to ensure that:

An appropriate process of independent expert review has demonstrated the research proposal to be worthwhile, of high scientific quality and good value for money.

Guidance on the various requirements for peer review are available on the RGO webpages, and/or directly from the funder. As a general rule, reviewers must be independent of the research team and the UoL, they must also be an expert in the field/a closely related field.

A template Peer Review form is available in Appendix 2.

If a researcher does not accept the comments within a Peer Review, it can be escalated to the RGO for further discussion. Where a protocol is changed following Peer Review, it is a good idea to maintain an audit trail of the changes made in the event this is required later on.

3.2.8 Site Feasibility Form

A thorough feasibility assessment must be conducted on each site involved in a research study to ensure that a site(s) has the capacity and capability to conduct the study in accordance with the research protocol and to meet agreed recruitment targets. Please refer to SOP S-1033 for further information about assessing site feasibility and for the feasibility form template.

3.2.9 Evidence of costing & funding

Evidence of adequate funding for the duration of the study must be provided. Where funding has been obtained from an external grant, this should be reported and maintained through Worktribe. Where all or part of the study is funded by an investigator's department, written confirmation of funds, in a named account, for the duration of the study must be provided. For longitudinal research, the CI must provide written confirmation of the funding plan to cover the duration of the study. Where funding is not secured, it is expected that the University department will underwrite the study to ensure completion. Where funding cannot be agreed or evidenced in full, the Sponsor and CI should discuss the feasibility and funding options, and Sponsorship may be refused. Discussions around funding will form part of the Sponsor Review Checklist and/or the Sponsor Risk Assessment (where one is required, see SOP S-1003) and Sponsor Green Light Process (SOP S-1025).

3.2.10 Investigator Brochure (IB)/Summary of Product Characteristics (SmPC)/Clinical Investigation Plan (CIP)

Where research involves Investigational Medicinal Products and/or non-CE Marked Devices, an Investigator Brochure (IB), Clinical Investigation Plan (CIP), and/or Summary of Product Characteristics (SmPC) must be provided as appropriate. Details of when these are required, and an IB Template, can be found in SOP S-1023. Where applicable, documents must be reviewed/approved by the relevant individual or department prior to submitting your Sponsor Application Form.

3.2.11 CV and appropriate training Certificates

A signed and dated CV for the Chief Investigator, Supervisor(s) and Student (where applicable) must be submitted alongside copies of valid relevant training certificates (e.g., GCP/consent). The HRA CV template should be used.

3.2.12 Contracts

The Sponsor Application Form will help researchers identify where additional contracts are required (i.e., with research collaborators, third party service suppliers, material and/or data transfer agreements etc). Where contract requirements are identified, these must be raised via Worktribe or by contacting REDContracts@le.ac.uk. It is expected that contracts and agreements are fully executed prior to the research starting where these contracts are integral to the running of the study.

It should be noted that only named individuals have the authority to sign contracts on behalf of the University. Researchers and staff must not sign agreements or contracts. Only the Head of Research Governance (or on their authority, their delegate) has the authority to sign the IRAS form and Sponsor-participating site agreements (i.e., model Non-Commercial Agreement (mNCA)/Organisation Information Document (OID)) on behalf of the University of Leicester.

4.0 The Sponsor Review Process

1. Upon receipt of an application, the RGO will complete a validation check. For applications to be considered 'valid', all relevant sections of the Sponsor Application Form must be completed and the application must be accompanied by all relevant supporting documents.

2. Notification of a valid application or a request for changes will be issued.

3. A Sponsor representative will review the application documents and, where necessary, will advise on changes required.

4. Where appropriate and in accordance with SOP S-1003, a Risk Assessment meeting to discuss the outcome of the initial Sponsor Review will be arranged with the CI and relevant members of the study team.

5. Comments on the documentation and any additional questions generated by the Sponsor Risk Assessment Form and/or Sponsor Review Checklist will be sent to the CI, or their delegate, for comment and document revision as appropriate.

6. A response to each question, revised documentation and/or any points of clarification will be required before a further review is conducted by the RGO. This process is iterative and only when all queries, required amendments, and points of clarification have been satisfied will the Sponsor Review process be complete.

7. Upon completion of the Sponsor Review process, the RGO will issue authorisation that the research study can be submitted for the applicable regulatory approvals.

Please note Sponsorship is 'in principle' until all relevant regulatory approvals, and management permissions (i.e., Confirmation of Capacity and Capability, or equivalent) have been received.

Sponsorship can be considered to be 'confirmed' once Sponsor Green Light has been issued.

5.0 Responsibilities

Responsibility	Undertaken by	Activity
Sponsor	Head of Research Governance or their Delegate	Confirm application is valid, complete Sponsor Review and communicate findings with the CI/Research team, conduct a Sponsor Risk Assessment and/or Sponsor Review Checklist (in accordance with SOP S-1003), authorise application for regulatory approvals.
Chief Investigator	Chief Investigator or their Delegate	Amend documentation as requested and return to the RGO, collaborate with the RGO during the completion of a Risk Assessment (if required), utilise RGO template documents.

6.0 Development and approval record for this document

This table is used to track the development and approval of the 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 	19/01/2024

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)
Oct 2013	2	Wendy Gamble	Supersedes S-1002 UoL Sponsor review process SOP. Document revised and renamed following review of sponsor processes.
April 2015	3	UoL RSMOG	SOP reviewed and revised. Changes to Logos. Additions to section 3, added sections 3.8 and 3.9. Addition to 3.5 to include use of social media. Addition to 3.6 to clarify need for peer review for student projects applying for adoption onto NIHR portfolio. Minor administrative changes to appendix references and dates /

			footer. Addition of Loughborough University to front page.
Oct 2016	4	Diane Delahooke	Update logos, reference to the HRA templates and Sponsor review checklist added. Text added in 3.7 to confirm funds available to studies funded in whole or part by dept.
Jan 2018	5	Michelle Muessel	Reviewed, updated address and added device information.
Sept 2021	5.1	Cat Taylor	Administrative changes
January 2024	6.0	Cat Taylor	SOP name changed from Initial Documentation Review Process to Sponsor Review Process Administrative changes Removal of monitoring and audit criteria table Removal of distribution record Removal of lists of documentation Addition of the requirement to use template documents Clarification around the Sponsorship Application review process (major updates to wording) Changes to Appendix 2 peer review form Removal of Appendix 1 – application form