



**University of Leicester Research Governance Office
Standard Operating Procedures**

SOP S-1040 UoL

**Sponsor Finance Process for Research Sponsored by the
University of Leicester**

Version 3.0 November 2024

Effective Date: December 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. For active studies there is no requirement to update appendices to the latest version.

1.0 Introduction and Scope

This Standard Operating Procedure (SOP) defines the process for identifying and documenting research project funding for all research Sponsored by the University of Leicester (UoL).

A key part of the Sponsor Review process is to ensure that a study has adequate resource and funding to deliver the study in line with the agreed protocol, contracts or agreements. When undertaking the Sponsor Review (and Risk Assessment process, where applicable), the Research Governance Office (RGO) expects documentation to include confirmation that adequate funding for the study is in place, or is in progress, before confirming University of Leicester (UoL) Sponsorship. In the case of CTIMP and Device studies, this includes costing in the provision for monitoring activity.

This SOP must be used by all those involved in the costing of research studies Sponsored by the UoL, and must be used in conjunction with the appropriate funder, Department of Health and NIHR guidance as relevant, and must take into account AcoRD (Attributing the Costs of health and social care Research and Development), and other University Financial Regulations.

2.0 Process

All areas of cost need to be identified, and adequate funding must be secured or in progress, during the project planning stages. In the event of CTIMPs or device trials, quotations for monitoring costs must be sought from the RGO in advance of a funding application, and must be included in the funding application. Failure to include adequate budget for monitoring activity may result in a refusal for the UoL to sponsor the trial and/or the requirement to provide funding from an alternative source (i.e., departmental funds).

2.1 External funding

Since January 2023, applications for external funding have, and continue to be, managed through Worktribe. The pre-award and contracts (PAC) team have laid out the following expectations and timelines which must be adhered to enable sufficient time for institutional costing, review and approval;

- **Minimum 6 Weeks (30 working days) to funder deadline:**
 - Clinical bids, bids with international partners, and other complex bids (as determined in consultation with the Research and Partnerships Development team):
 - Notify the PAC team of intention to apply for funding, with funder deadline.
 - PAC team will contact you to support some elements of the costing.
 - For complex and/or high value submissions, applicants (i.e., Chief Investigator (CI)) can access additional support for proposal development and stakeholder management via the Research and Partnerships Development Team.
- **3 Weeks (15 working days) to funder deadline:**
 - All Worktribe records (and supporting documents) to be submitted to the PAC team. *It is not expected that substantial changes to the required resources will be made beyond this point.*
 - PAC team will work with the applicant to refine costs in line with funder requirements, UoL policies and perform any required due diligence and funder specific compliance checks.
 - Should further refinement be required following the PAC team checks, they will work with the applicant or their delegate to achieve these.
- **1 Week (5 working days) to funder deadline:**

- Worktribe record to be finalised, with copy of the application attached and submitted to Head of Department/School/College for approval.
- **2 working days to funder deadline:**
 - Application to be fully completed on funder portal ready for final checks and onward submission to funder by PAC.

Further guidance can be found within the 'Help' tab on Worktribe.

2.1.1 Exceptions

On the rare occasion that a funder issues a short notice deadline, applicants must liaise immediately with PAC who will support where possible.

2.2 Internal Funding

Where the study is to be internally funded using College or Departmental funds, the CI must ensure that adequate funding is ring-fenced. Confirmation of this should be secured from the appropriate Head of Department (HoD)/School (HoS)/College (HoC) and evidence retained. Confirmation of funding must be communicated to the RGO to enable the Sponsor review process to be completed.

3.0 Procedure and Responsibilities for externally funded studies:

3.1 Project Costings stage:

| Responsibility | Undertaken by | Activity |
|----------------|-------------------------|--|
| CI | CI or delegate | Before submitting a research funding application, identify the full economic costs for the proposed study. |
| CI | CI or delegate | For NHS costs: a) refer to the NHS research costs form (Appendix 1) to ensure proper identification of NHS research, support and treatment costs – advice should be sought from the NIHR Research Delivery Network (RDN) about the completion of the SoECAT. b) consult with relevant departments and vendors e.g. individual NHS trust involved in the research, clinical trials units, pharmacies and obtain evidence of agreed research costs. c) For CTIMP and Device trials, seek a monitoring quote from rgosponsor@le.ac.uk. |
| CI | CI or delegate | Make contact with the pre award and contracts team (PAC) as early as possible and by the timelines stated in section 2.0 by submitting a full project costing application via Worktribe. |
| RED | PAC team | Check costings and approve if appropriate, or request further information from CI if required to enable this. |
| RED | PAC team/HoD/HoS HoC | Review and sign off costings. |
| RED | PAC team or delegate | Submit application for funding |
| CI/PAC team | CI or delegate/PAC team | Ensure Worktribe record is appropriately maintained |

3.2 Notification of award stage:


| Responsibility | Undertaken by | Activity |
|----------------|---|--|
| CI | CI or delegate | To update Worktribe with the status of the funding award e.g. in progress, in second stage, rejected, and provide evidence as necessary. |
| CI | CI or delegate | If external funding awarded but no funding application completed, identify all study costs and complete Worktribe application |
| RED | PAC team | RED starts to set up the award and informs RGO of award |
| RED | PAC team | RED agrees funding offered on funder terms (or after negotiation) in accordance with RED procedures |
| RGO | Head of Research Governance or delegate | RGO conducts Sponsor Review |
| RED and RGO | Staff in RSS | If awarded amount is lower than requested, notify CI and RGO |
| RGO | Head of Research Governance | If notified by RED that awarded amount is lower than that applied for, decide whether study can be Sponsored with available budget |
| CI | CI or delegate | Where there is a shortfall in budget awarded and the CI decides to use internal College or Departmental funds, then Procedure 4 in Table iii below should be followed. |
| CI/PAC team | CI or delegate/ PAC team | Ensure Worktribe record is appropriately managed with evidence of funding retained. |

4.0 Procedure and Responsibilities where study is funded from internal Departmental or College Funds:

| | Responsibility | Undertaken by | Activity |
|---|----------------|----------------|---|
| 1 | CI | CI or delegate | Identify the full costs of the study in a similar way as if seeking external funding and identify source from where the funds are coming |
| 2 | CI | CI or delegate | For NHS costs: d) refer to the NHS research costs form (Appendix 1) to ensure proper identification of NHS research, support and treatment costs e) consult with relevant departments and vendors e.g. individual NHS trust involved in the research, clinical trials units, pharmacies and obtain evidence of agreed research costs. For CTIMP and Device trials, seek a monitoring quote from rgosponsor@le.ac.uk. |
| 4 | CI | CI or delegate | Seek confirmation from the appropriate Head of Department/ College office that the funds have been identified and secured. Evidence of this must be retained. |

5.0 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 Management and Operations Group (RSMOG) | Professor Nigel Brunskill  | 27/11/2024 |

6.0 Review Record

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

| Date | Issue Number | Reviewed By | Description Of Changes (If Any) |
|---------------|--------------|-------------|---|
| May 2016 | 2 | RSMOG | Minor administrative changes to text and footer, change to logos, addition of Loughborough University to front page and changes to the new division name |
| Sept 2021 | 2.1 | Cat Taylor | Administrative changes |
| November 2024 | 3.0 | Cat Taylor | <ul style="list-style-type: none"> • Removal of office address • Removal of distribution record • Review schedule updated to every 3 years • Administrative Changes • Change from LUCRE to Worktribe for externally funded studies • Applicant Worktribe timelines and expectations added • Removal of reference to Research Governance Framework – replaced with UK Policy for Health and Social Care Research • Removal of Appendix A from SOP document as this is already a standalone appendix (Appendix 1) |