



**UNIVERSITY OF LEICESTER
&
UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST
JOINT RESEARCH & DEVELOPMENT SUPPORT OFFICE
STANDARD OPERATING PROCEDURES**

**University of Leicester (UoL) Research Governance Office
SOP S-1040 UoL**

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

Version 2.1 September 2021

OFFICE BASE

Research Governance Office
University of Leicester
Academic Department
Leicester General Hospital
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Effective Date October 2021

1. Introduction

This Standard Operating Procedure (SOP) defines the process for identifying and documenting research project funding prior to the start of a study requiring University Sponsorship as defined by the Department of Health (DoH) Research Governance Framework (version 2, 2005) or the Medicines for Human Use (Clinical Trials) regulations 2004.

This SOP must be used by Chief Investigators, Department Managers, Research and Enterprise Division (RED), College of Medicine, Biological Sciences and Psychology (MBSP) College Accountant and Research Governance Office and must be used in conjunction with funder guidance and where applicable, Department of Health and NIHR guidance, including AcORD, and other University Financial Regulations.

When undertaking the Sponsor review and risk assessment process, the Research Governance Office expects documentation to include confirmation that adequate funding for the study is in place before confirming University Sponsorship.

The purpose of this SOP is to ensure appropriate costings are completed and funding is in place to conduct the study. This will enable the Research Governance Office to undertake appropriate research governance checks to confirm Sponsorship for a given University led research study.

2. Scope

This SOP applies to all research sponsored by the University of Leicester.

3. Responsibilities

A Chief Investigator (CI) intending to conduct a new research study is expected to:

- (a) Identify all research study costs and, where appropriate, NHS support and treatment costs in accordance with funder, AcORD, and University guidance;
- (b) If the study involves the use of NHS premises, staff or patients then contact the R&D Office of the appropriate Trust, in the first instance.
- (c) When seeking external funding refer to the NHS research costs form (attached as Appendix A) and consult with appropriate DoH or NIHR guidance;
- (d) Consult and check with relevant departments (such as individual Trust's pharmacies) who will be involved in the study before formal commitment or request for research funding is submitted;
- (e) Generate a full project costing through LUCRE and submit for approval (when applying for external funding);

(f) Where external funding is secured, ensure that adequate agreements are in place before starting any new research;

(g) Where study is to be funded from internal departmental or College sources to confirm with College Accountant, College of MBSP prior to the start of the study that adequate funds are available to deliver the study. Evidence of this confirmation must be communicated to the Research Governance Office.

The University expects Chief Investigators to ensure that all costs are identified and adequate funding secured before the start of the study. Final Sponsor confirmation is not released until the funding contract is signed with the Funder. The Research Support Services team (RSS) in RED can advise on funder rules to ensure maximisation of cost recovery.

Where the study is to be internally funded using College or Department funds, the Chief Investigator must ensure that adequate funding is ring-fenced for that study and confirmation of this should be secured from the College Accountant at MBSP. Confirmation of College funding must be communicated to the Research Governance Office to enable the Sponsor review process to be completed. College Accountant can advise on ring-fenced funds.

4. Procedure and Responsibilities for externally funded studies:

Project Costings stage:

Table i

	Responsibility	Undertaken by	Activity
1	CI	CI or delegate	Before submitting research funding application, identify the full economic costs for the proposed study
2	CI	CI or delegate	For NHS costs: (a) refer to the NHS research costs form (attached) to ensure proper identification of NHS research, support and treatment costs (b) seek approval from R&D Finance Manager of the appropriate NHS body (c) arrange for copy of email approvals from R&D Finance Manager of the appropriate NHS body to be sent to RED and copied to the Research Governance Office. Email confirmation from R&D Finance Manager of appropriate NHS body should be sufficient.
3	CI	CI or delegate	If using Division of Biomedical Services, request written confirmation of costs and send to RED
4	CI	CI or delegate	If using UoL Clinical Trials Unit, obtain written quote from CTU and send to RED, along with project costings, and copy to the Research Governance Office
5	CI	CI or delegate	Contact Governance Office for sponsorship and governance costs including monitoring and archiving by email (rgosponsor@le.ac.uk)

	Responsibility	Undertaken by	Activity
6	CI	CI or delegate	If there are other collaborator costs ensure these are obtained from the collaborator Research office and properly captured on the LUCRE form
7	CI	CI or delegate	Having captured the full economic costs of the project, submit costings for RED approval using LUCRE
8	RED	Staff in RSS	Check costings and approve if appropriate, or request further information from CI if required to enable this.
9	CI	CI or delegate	On approval of costs, obtain signatures of Chief Investigator and Head of Department on the Project Approval Form and send to RED for record keeping
10	RED	Staff in RSS	Store Approval Form with funding application documentation

Notification of award stage:

Table ii

	Responsibility	Undertaken by	Activity
1	CI	CI or delegate	Funder award notification to agree to fund research project sent to appropriate team in RED (depending on source of funding): If public sector funding – sent to Research Grants Team in RSS If private or industry funding – sent to Contracts Team in RSS
2	CI	CI or delegate	If external funding awarded but no funding application completed, identify all study costs and complete LUCRE costing
3	RED	Staff in RSS	RED starts to set up the award and inform Research Governance Office of award
4	RED	Staff in RSS	RED agrees funding offered on funder terms (or after negotiation) in accordance with RED procedures
5	Research Governance Office	Research Governance Manager	Research Governance Office conducts Sponsor Review
6	RED and Research Governance Office	Staff in RSS and	If awarded amount is lower than requested notify Chief Investigator and Research Governance Office
7	Research Governance Office	Research Governance Manager	If notified by RED that awarded amount is lower than that applied for, decide whether study can be Sponsored with available budget

	Responsibility	Undertaken by	Activity
8	CI	CI or delegate	Where there is a shortfall in budget awarded and the Chief Investigator decides to use internal College or Departmental funds, then Procedure 5 in Table iii below should be followed.

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

Table iii

	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 - use costing form – and seek approval from appropriate NHS body
4	CI	CI or delegate	Seek confirmation from MBSP College office that funds identified in LUCRE costing are secured for the study
5	MBSP College Accountant	MBSP College Accountant	Formal approval that costs for the study ring-fenced is required from MBSP College Accountant before Research Governance Office can complete Sponsor review process.
6	MBSP College Accountant	MBSP College Accountant	Send confirmation of formal approval by MBSP College Accountant to Research Governance Office
7	CI	CI or delegate	Ensure confirmation of ring-fenced funds to Research Governance Office as evidence that funding can utilised for the proposed study.

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)
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

Distribution Record

Date	Name	Department	Received

APPENDIX A: NHS RESEARCH COSTS FORM

Costing Considerations for Research where the University will act as Sponsor:

Staffing Costs

- Does the study take place on NHS premises
- Are any NHS staff involved in the research, i.e; any ward or clinic staff expected to distribute study information or assist with participant identification or carry out any study related procedures?
- Do any staff need to be employed specifically to do the research?

Treatment Costs

You should seek advice about treatment costs from NHS Trust Finance Office. These may not be funded by the grant – but could prevent the study going ahead if there are significant unplanned additional treatment costs for the NHS

Service Support Costs

You should seek advice about service support from NHS Trust. These include:

- Screening
- Consenting costs
- Patient Safety Costs

Research Costs

- Patient refreshments
- Training
- PPI costs (patient involvement)
- Travel / Parking expenses
- Clinical Consumables, blood bottles, syringes etc
- Administrative Consumables, postage, stationery etc
- Payments to participants
- Payments to Primary Care practices for assistance with research, eg; database search to identify potential participants (for studies not eligible to receive service support costs)
- Courier costs
- Costs of study procedures, eg; X-rays, MRI, ECG etc
- Pharmacy support
- Radiology support
- Laboratory support both NHS labs and external labs (may be in UK or global)
- Any other external providers, eg; CTU
- Translation
- Counselling

Study in GP surgeries

Where study is being planned to be conducted in GP surgeries, then the relevant CCG should be contacted.

For multi-site studies some or all of these costs may apply at other sites.

Associated Study Costs (Sponsor responsibilities)

- Regulatory fees
- Archiving
- Monitoring and audit –

- Is there enough money for the study duration?
- Insurance – additional premium may be due depending on the type of study and risk. Please refer to the Insurance SOP Reference S-1017 UoL

YOU MUST SEEK APPROVAL FOR NHS COSTS FROM RELEVANT R&D OFFICE AT THE NHS TRUST BEFORE GRANT SUBMISSION

NHS Trust R&D Contact Details:

For **UHL:** Martin Maynes, UHL R&D Finance Lead on 0116 2588242, or via email at martin.maynes@uhl-tr.nhs.uk

For **other NHS Trusts:** [Link to R&D Forum website](#)