1. Introduction

This Standard Operating Procedure (SOP) describes the requirements for obtaining finance approval for all research HOSTED by University Hospitals of Leicester NHS Trust (UHL) or where the UHL is a Research SITE. Its purpose is to ensure that all HOSTED studies are adequately funded to completion and do not have any unmet cost implications to UHL. If your study is Sponsored by the UHL the SOP S-1034 UHL must be consulted.

The outcome is that the Trust can receive adequate assurance that all research studies are appropriately funded and that there are mechanisms in place to recover any income due.

2. Scope

This SOP applies to all research studies that are either HOSTED by the UHL or where the UHL is acting as a Research SITE.

3. Advice

Researchers are encouraged to contact the Finance Team at the earliest possible opportunity. This could be at first contact from the Sponsor organisation, following contact from a Clinical Research Organisation (CRO) or via the Clinical Research Network (CRN). It is important to be sure that all UHL costs are identified and covered by the funding available.

Finance Team support is available for:

- Establishing staff & non-pay costs
- Establishing income associated with research
- Attributing the research costs in accordance with Attributing costs of Health & Social Care Research & Development (AcORD)
- Profiling expenditure across financial years
- Liaising with Higher Education Institutions (HEI's) and third parties to establish costs and cost recovery
- General financial advice
- Completion of Commercial costing template
- Liaison with Clinical Research Network
- Liaison with Study Support Services
- Confirmation of NHS Costs for grant applications
- Financial management following approval
- Liaison with Funders
- Review of contracts

4. Obtaining Finance Approval

A key part of the authorisation process to achieve permission for research to commence at UHL is to ensure that a study has adequate resource and funding to enable delivery in accordance with the Protocol and study Contract. The Finance Team therefore are required to confirm the funding by providing finance approval.

In order for the Finance Team to undertake a finance review, the following documents are the minimum required:

- Final version of Protocol (or as close to)
- Organisation Information Document (OID) / Schedule of Events Cost Attribution Template (SOECAT) (if applicable)
- EDGE ID for the Study

In addition when commercially funded & sponsored a final copy of the Commercial Costing Template must be provided.

If applicable and available the following may also be required:

- Study costings
- IRAS Forms
- Grant application
- Final draft contracts
- Written confirmation of funding award

4.1 Finance approval process

On receipt of a complete application for finance approval, the Finance Team will review the submitted documentation, follow up any queries or outstanding issues, and make one of the following decisions:

- Approval
- Rejection
- Further action / Information required

Finance approval will be confirmed by email from the UHL R&I Finance Team. Confirmation will be recorded within the EDGE system by completion of relevant Entities and Workflows. The relevant Entities and Workflows must be fully completed in accordance with the 'EDGE Finance Attributes / Workflows Working Instructions' document which is available in General Documents in the EDGE System.

4.2 Process following Rejection of Finance Approval

If your application has been rejected, the Finance Team will feedback clearly the reasons for the rejection and provide relevant support on re-submission.

4.3 Process following Request for Further Action / Information Required

The Finance Team will clearly state action / information required. If action / information received is adequate, finance approval will then follow. The subsequent approval will be recorded on EDGE as detailed in 4.1.

5. Responsibilities

	Responsibility	Undertaken by	Activity
1	Principal Investigator (PI) / Study Team	Principal Investigator (PI) / Study Team	Provide all relevant documentation to the Finance team to enable a finance review
2	Finance Team	Finance Team	Conduct a review of finance and communicate the outcome to the PI / Study Team
3	PI/ Study Team	PI / Study Team	Act on request for further information if required.
4	Finance Team	Finance Team	Provide finance approval when appropriate to do so

6. Legal Liability Statement

Guidelines or Procedures issued and approved by the Trust are considered to represent best practice. Staff may only exceptionally depart from any relevant Trust guidelines or Procedures and always only providing that such departure is confined to the specific needs of individual circumstances. In healthcare delivery such departure shall only be undertaken where, in the judgement of the responsible healthcare professional it is fully appropriate and justifiable – such a decision to be fully recorded in the patient's notes and in the research site file.

7. Supporting Documents and Key References

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8. Key Words

Research, Innovation, Volunteers, Participants, CTIMPS, Trials, Finance, CRO, CRN, Funding, Grants, SOECAT, IRAS

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

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT			
Author / Lead Officer:	Carolyn Maloney & Martin Maynes	**Job Title:** Head of Research Operations / R&I Finance Lead	
Reviewed by:	R&I Governance Meeting		
Approved by:	Professor Nigel Brunskill	**Date Approved:** 16/2/21	

REVIEW RECORD			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**
July 2016	2	CM, MM	Review of process, addition of EDGE completion document. Consistency checking
February 2017	3	CM	Update to Logo
February 2019	4	CM /MM	NO changes
February 2021	5	LW MM	Review and update, Reformatting to new template

DISTRIBUTION RECORD:			
Date	**Name**	**Dept.**	**Received**