

## **1. Introduction**

This Standard Operating Procedure (SOP) describes the requirements for obtaining finance approval for all research sponsored by the University Hospitals of Leicester NHS Trust (UHL).

Prior to confirmation that the UHL will accept responsibility as a Sponsor, the Sponsor Review process must be undertaken. This is a comprehensive review of the whole proposal and includes a Risk Assessment. Further information can be found in SOP S-1002 UHL, & SOP S-1003 UHL.

A key part of the Sponsor review process is to ensure that a study sponsored by UHL has adequate resource and funding to deliver the study in line with the agreed Protocol, and any contracts or agreements. All partners involved in research require that the Sponsor assures adequate funding is in place. The Finance Team therefore are required to confirm the funding by providing finance approval.

Its purpose is to ensure that all SPONSORED studies are adequately funded to completion and do not have any unmet cost implications to UHL. If your study is HOSTED by the UHL the SOP C-2019 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 Sponsored by the UHL.

## **3. Advice**

All researchers are encouraged to contact the Finance Team at the earliest possible opportunity. This could be at first inception of ideas but must be before any bids or applications for funding are made.

Support is available for:

- Establishing staff & non-pay costs
- Establishing income associated with research
- Attributing the research costs in accordance with AcORD
- Profiling expenditure across financial years
- Liaising with HEI's and third parties to establish costs and cost recovery
- General financial advice
- Liaison with funding bodies
- Liaison with Study Support Services

## **4. Obtaining Finance Approval**

In order for the Finance Team to undertake a finance review, the following must be provided by the Chief Investigator.

The minimum documents required:

- Final version of Protocol
- Full Data Set from IRAS

If applicable and available the following will also be required:

- Study costings
- Grant application
- Final draft contracts / Organisation Information Document (OID) and Schedule of Events Cost Attribution Template (SOECAT)
- Written confirmation of funding award
- Details of all additional sites

#### 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.

Once the Finance Team has provided approval, advice and instruction will be provided on the financial management requirements for the study activity.

#### 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	Chief Investigator	Chief Investigator	Make contact with the finance team as early as possible
2	Chief Investigator	Chief Investigator	Provide relevant documentation for finance review
3	Sponsor	Sponsor	Confirm finance has relevant documentation – if not, provide access to documentation used in Sponsor review
4	Finance Team	Finance Team	Review documentation from a finance perspective and make a decision. Communicate the decision to the Chief Investigator & Sponsor.
5	Chief Investigator	Chief Investigator	Act on finance decision & if necessary open dialogue to address queries
6	Finance Team	Finance Team	Confirm finance decision in writing copied to the Sponsor

	Responsibility	Undertaken by	Activity
7	Sponsor	Sponsor	On receipt of finance approval, include in Sponsor documentation and update EDGE

## **6. Supporting Documents and Key References**

SOP S-1002

SOP S-1003

SOP C-2019

## **7. Key Words**

Research, Innovation, Volunteers, Participants, CTIMPS, Trials, Finance, IRAS, OID, SOECAT, GCP, AcCORD

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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

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<b>Author / Lead Officer:</b>	Carolyn Maloney & Martin Maynes		<b>Job Title:</b> Head of Research Operations / Research Finance Lead
<b>Reviewed by:</b>	R&I Governance Meeting		
<b>Approved by:</b>	Professor Nigel Brunskill		<b>Date Approved:</b> 16/3/21
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Date	Issue Number	Reviewed By	Description Of Changes (If Any)
July 2016	2	CM, MM	Consistency check. Added process for EDGE
February 2017	3	CM	Update to logo
September 2018	4	CCL LW, MM	Update to R&I logo General review, no updates
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