

1. Introduction

1.1 This Standard Operating Procedure (SOP) describes the procedures used by the University Hospitals of Leicester NHS Trust (UHL) Research Office when providing and managing agreements with Third Parties, where the UHL is the HOST Organisation for research. The outcome is that the UHL is able to manage the ongoing contractual process throughout the duration of a research Study.

1.2 It is essential that clear agreements describing allocation of roles and responsibilities are reached and documented prior to any Study-related procedure commencing. In addition, it is important that research related contracts or agreements are signed only by those authorised to do so.

2. Scope

2.1 This SOP applies to all staff, and any external individual who conduct research where UHL is the HOST Organisation or a research SITE.

3. Procedure

3.1 It is expected that during the authorisation process, the Sponsor will provide UHL with relevant Site agreements. Agreements may include Contracts (both model and bespoke), Material Transfer Agreements, and / or Organisation Information Document (OID) & Schedule of Events Costings Attribute Template (SOECAT). It is a requirement that before services commence at UHL written agreement between the UHL and the Sponsor be fully executed. Where it is necessary for additional parties to be signatories to agreements, they will be fully involved in the negotiation discussions.

3.2 The UHL R&I Office Contracts Manager or their delegate will review contracts and communicate as required with the Sponsor or appropriate contact. The R&I Office Contracts Manager or their delegate will populate the EDGE Database Contracts Attributes and Workflows and Atamis Database. Before sign off, UHL R&I Finance must have provided approval for the costing of the research.

3.3 It is of paramount importance that each contract target is negotiated appropriately. It is expected that each contract will show a range target. The lower number must always appear in the contract and also in the SITE Level within EDGE. Ideally the target range should be 1 – X.

3.4 By signing the agreements, UHL is confirming Capacity and Capability to deliver the research. Agreements will be signed on the same day or very close to the date that the UHL confirm Capacity and Capability.

3.4.1 All research related contract or agreements must be signed only by the authorised signatories for UHL:

- Director of Research & Innovation
- Associate Director of Research & Innovation
- R&I Chief Operating Officer
- R&I Deputy Chief Operation Officer

3.5 Agreements that are signed by other individuals may not be valid and may put UHL at unnecessary risk.

3.6 Once fully signed, ONE (1) original will be kept by UHL Research Office, ONE (1) original will be kept by the Sponsor and ONE (1) original/or copy will be placed in the Investigator Site file.

3.7 This SOP does not cover employment or Human Resources related contracts.

4. Responsibilities

	Responsibility	Undertaken by	Activity
1	PI / Research Team	PI / Research Team	Forward all draft contracts to RIContract@uhl-tr.nhs.uk
2	R&I Office Contracts Manager	Contracts Manager or their delegate	Ensure that contracts are negotiated, the costings / finances have been agreed and signed off as appropriate
3	R&I Office	Contracts Manager or their delegate	To ensure that all relevant departmental staff involved in the study, and UHL support staff are adequately consulted during negotiations and prior to the contract execution.
4	R&I Office	Contracts Manager or their delegate	Ensure Agreements are filed & retained appropriately in the R&I Office, and a fully executed document sent to the research team for filing in investigator site files

5. Who Guideline Applies To

5.1 All staff within UHL and external to UHL who are delivering research.

6. Education and Training

6.1 The SOP is detailed so the process can be clearly followed. No flowchart is provided / required.

7. Education and Training

7.1 None.

8. Monitoring Compliance

Key Performance Indicator	Method of Assessment	Frequency	Lead
All research Hosted by UHL has appropriate contracts in place.	Included in the monitoring / audit programme.	Random audits / monitoring conducted on 10% of research activity.	R&I Deputy Chief Operating Officer

9. Supporting Documents and Key References

None

10. Key Words


Research, Innovation, EDGE, REC, Contracts, SOECAT, Agreements

11. Contact and Review Details

CONTACT AND REVIEW DETAILS	
Guideline Lead (Name and Title) Lisa Wann R&I manager	Executive Lead Medical director
Details of Changes made during review: Review and update	

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

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Date	Issue No.	Reviewed By	Description Of Changes (If Any)
July 2016	2	CM, RP, DW	Update of wording.
February 2017	3	CM	Update to logos.
February 2019	4	CM, LW	Consistency check. Update to Logo
February 2020	5	CM	Revision to target setting
July 2021	6 & 7	LW	Update and review, Update to new trust template
Feb 2022	8	LW CS DW	Update
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