

1. Introduction

This Standard Operating Procedure (SOP) describes the procedures used by the University Hospitals of Leicester NHS Trust (UHL) when managing amendments to agreements with Third Parties, where the UHL is the Sponsor.

The outcome is that the UHL is able to manage the ongoing contractual process throughout the duration of a research study.

2. Scope

This SOP applies to all contracts relating to research sponsored by the UHL that require amendment.

3. Procedure

It is expected that where appropriate during the UHL Sponsor Green Light and Risk Assessment process for amendments SOP S-1017 UHL, required revisions to existing Third Party and NHS site agreements will be identified in order for appropriate negotiations to begin.

It is a requirement that before any changes to contracted services commence an amended agreement between the UHL and the Third Party must be fully executed. In exceptional circumstances, and where it is necessary for a Third party to commence revised activity prior to a fully executed amended agreement, a letter of intent will be provided to allow these activities to begin.

The Head of Research Operations or their delegate will forward details of amendments to the Contracts Team to review and determine any necessary changes.

The contracts amendment process is included within the Amendment process on the EDGE system as appropriate and the relevant Attributes and Workflows completed.

3.1 NHS Site Agreements – no transfer of funds

If required, where it has been confirmed that there remains no transfer of funds from the UHL as Sponsor to an NHS Site, the Contracts Team will generate appropriate confirmation.

3.2 NHS Site Agreements – with transfer of funds

Where it has been confirmed that there are funds to be transferred from the UHL as Sponsor to an NHS Site, the Contracts Team will generate appropriate amendments, lead negotiations with the site and manage the agreement process to achieve full execution of the amended agreements. Once fully signed, a copy must be placed in the Investigator Site File at the NHS site, one to be placed in the Trial Master File and one to be saved within the RED LEVEL of the EDGE Instance for the site.

3.3 Third Party / Vendor Agreements

Where amendments to agreements with Third Parties providing services, funding, equipment, medicinal products etc. have been identified, details will be forwarded to the Contracts Teams. Negotiations to full execution will be managed by the Contracts Team.

Two original amended agreements must be signed by all parties. One to be kept by the Third Party / Vendor, one for the Sponsor, with copies sent to the Chief Investigator for inclusion in the Trial Master File. In addition a copy must be stored in the GREEN LEVEL on the EDGE System

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

4. Responsibilities

	Responsibility	Undertaken by	Activity
1	UHL Sponsor	Contracts Team	Confirm the necessity for amendments to Third Party Agreements during the Sponsor Risk Assessment and Green Light Process for amendments.
2	UHL Sponsor	Contracts Team	Where required generate an amendment to contract document using appropriate template where there are revisions but no transfer of funds to NHS sites.
3	UHL Sponsor	Contracts Team	In cases where transfer of funds exists, generate, negotiate and approve amendment to the original Agreement where there are revisions and / or transfer of funds to NHS sites.
4	UHL Sponsor	Contracts Team	Ensure that all Third Party contract amendments are drafted, reviewed, negotiated and approved.
5	UHL Sponsor	Contracts Team	To ensure that all relevant staff involved in the study, and support staff are adequately consulted during negotiations and prior to the contract amendment execution.
6	UHL Sponsor	Contracts Team	Ensure amendments to Third Party Agreements are filed / retained

5. Procedure following invitation to participate

Key Performance Indicator	Method of Assessment	Frequency	Lead
All research sponsored by UHL has appropriate contracts in place.	Included in the monitoring / audit programme.	Random audits / monitoring conducted on a risk based approach determined by research activity	Head of Research Operations or delegate

6. Supporting Documents and Key References

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7. Key Words

Research, Innovation, Volunteers, Participants, CTIMPS, Trials, Contracts, TMF, Amendments

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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		Job Title: Head of Research Operations
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)
May 2015	2	Carolyn Maloney	Change of Logo and corporate identity
August 2016	3	CM, DW	Consistency check, addition of EDGE process
February 2017	4	Carolyn Maloney	Update to logo.
May, October 2018	5	CM, LW, DW, RP CCL	Include EDGE in process. Update to R&I logo
February 2021	6	LW DH DW	Update and review
DISTRIBUTION RECORD:			
Date	Name	Dept.	Received

