1. Introduction

This Standard Operating Procedure (SOP) describes the procedures used by the University Hospitals of Leicester NHS Trust (UHL) when providing and managing agreements with external parties.

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

It is essential that clear agreements describing allocation of roles and responsibilities are reached and documented prior to any study-related procedure commencing with all relevant individuals and organisations involved.

2. Scope

This SOP applies to all staff involved in the conduct or management of research at UHL.

3. Procedure

3.1 Sponsored trials

3.1.1 It is expected that during the UHL Sponsor Review and Risk Assessment process that the Chief Investigator, all third parties, collaborators, support services, clinical trials units, universities and any other NHS organisations/sites are identified to enable the appropriate contracts to be established.

3.1.2 Agreements may include, but are not limited to those between:

- UHL and Participating Organisation(s) – Research sites
- The UHL and funder(s)
- UHL and organisations providing a service (e.g. Statistical Support, CRO, Monitoring, CTU etc.)
- UHL and providers of medicinal products or equipment
- UHL and any collaborators not covered above
- R&I and internal support services
- R&I and the Chief Investigator

3.2 Trials where UHL is a participating site

3.2.1 It is expected that the Sponsor will provide UHL with the relevant agreements and use the national templates wherever possible.

3.2.2 As part of the confirmation of Capacity and Capability (C&C) process, the PI will be required to sign a PI Roles and Responsibilities form, this will be sent out by the R&I Contracts delegate, and must be signed before the study can receive confirmation of C&C. Agreements will be signed on the same day or very close to the date that the UHL confirm C&C.

3.3 All contracts, where UHL is the sponsor or the host:

3.3.1 Contracts and agreements are used to document and agree aspects of the relationship between the UHL and third party organisation(s), including, but not limited to:

- Roles and Responsibilities
- Financial and legal considerations including indemnity
- Termination considerations
- Standards of service
- Regulatory obligations including GDPR
- Intellectual property and publication considerations
- Confidentiality considerations

3.3.2 The R&I Contracts Team will generate and manage the contract process to full execution. Contracts will be submitted for signature. Those designated below are deemed authorised signatories for UHL R&I:

- R&I Director
- R&I Deputy Director
- R&I Director of Operations
- R&I Deputy Director of Operations

3.3.3 Research related contracts signed by other signatories may be deemed void and invalid.

3.3.4 Once fully signed, a copy of the executed contract(s) will be retained in the core R&I Office and also in the Trial Master File (TMF) and Investigator Site File (ISF) where applicable.

3.3.5 Contracts and agreements should be proportionate to the level of risk associated with the study and the type/nature of other organisation(s) involved. It is expected that the UHL will use nationally approved standard templates where applicable and appropriate.

3.3.6 The Research Contracts Manager or delegate should ensure that all applicable EDGE workflows, FLORENCE binders, forms and data are complete for the contracting process.

3.3.7 Contracts may need to be amended at times and this will be managed by the Research Contracts team.

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

8. Monitoring and Audit Criteria

Key Performance Indicator	Method of Assessment	Frequency	Lead
All research sponsored or hosted by UHL has appropriate contracts in place.	Included in the monitoring/audit programme.	Random audits/monitoring conducted on a risk based approached according to research activity.	R&I QA Manager

9. Key Words

Research, FLORENCE, EDGE, Contracts, Agreements, Sponsor, Host, Data Protection.

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