1. Introduction

1.1 This Standard Operating Procedure (SOP) describes the procedures used by the University Hospitals of Leicester NHS Trust (UHL) when providing and managing agreements with Third Parties, Chief Investigator Declarations and other Service Level Agreements where the UHL is the Sponsor of research.

1.2 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

1.3 NB for the purpose of clarification a Third Party in the context of this SOP will be deemed any individual or organisation not considered an employee or subsidiary of the UHL. This may include the Leicester Clinical Trials Unit and the University of Leicester. It may also be necessary to develop Service Level Agreements between R&I and internal departments at UHL e.g. Pathology Services, Pharmacy etc.

2. Scope

2.1 This SOP applies to all staff, and any external individual who approach the UHL to request that the organisation act as Sponsor for research activity.

3. Procedure

3.1 It is expected that during the UHL Sponsor review and Risk Assessment process the Chief Investigator, all Third Parties, collaborators, support services, Clinical Trials Units, Universities and any other NHS organisations / sites will be identified in order for appropriate agreement negotiations to begin. It is a requirement that before services commence a written agreement between the UHL and the Third Party be fully executed. Where it is necessary for a Third party to commence pre-trial set up activity, a letter of intent will be provided to allow these activities to begin.

3.2 The Research & Innovation Deputy Chief Operating Officer (RIDCOO) or delegate conducting the Sponsor review will populate the relevant information in EDGE attributes or workflows and notify the R&I Contracts Team for action to be taken.

3.2.1 Third Party Agreements may include, but are not limited to those between:

a. The UHL and Participating Organisation(s) – Research sites
b. The UHL and another Co-Sponsor or Joint Sponsor
c. The UHL and Funder (s)
d. The UHL and Organisations providing a service (e.g. statistical support, CRO, Monitoring, CTU etc.)
e. The UHL and providers of medicinal products or equipment
f. The UHL and any collaborators not covered above
g. R&I and internal support services
h. R&I and the Chief Investigator

3.3 Third Party Agreements include contracts, clinical trial agreements, service level agreements, roles and responsibilities documents, forms of work or similar documents.

3.4 The form of any Third party agreement 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.

3.5 The contracts process is managed through the EDGE/Atamis system(s) as appropriate and all relevant Attributes and Workflows completed.

3.6 Where the study is a multi-centre study a multi-centre check list (Appendix 2) will be completed in collaboration with a 3 party (eg: a CTU) to ensure the responsibilities are agreed at the outset.
The Contract and Review process is attached at Appendix 1.

3.7 Third Party / Vendor Agreements
Third Party Agreements are used to document and agree aspects of the relationship between the UHL and Third Party organisation(s), including, but not limited to:

a. Roles and Responsibilities
b. Financial and legal considerations including indemnity
c. Termination considerations
d. Standards of service
e. Regulatory obligations including Data Protection
f. Intellectual property & publication considerations
g. Confidentiality considerations

3.8 The 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:

- Director R&I,
- Associate Director R&I
- R&I Chief Operating Officer
- R&I Deputy Chief Operating Officer

3.9 Research related contracts signed by other signatories may be deemed void and invalid if signed by other individuals

3.10 Once fully signed, ONE (1) will be kept by UHL Sponsor, ONE (1) to be kept by the Third Party and ONE (1) to be placed in the Trial Master file.

3.11 In cases of Multi-Centre studies, it is recommended that a copy be kept in the Investigator Site File at each site. A copy must be retained by UHL Sponsor within the EDGE instance for each site (RED LEVEL).

3.12 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 Third Party Agreements during the Sponsor Risk Assessment and Green Light Process
2	UHL Sponsor	Contracts Team	Ensure that all Third Party agreements are drafted, reviewed, negotiated and approved, ensuring that responsibilities of all parties are accurately documented.

	Responsibility	Undertaken by	Activity
3	UHL Sponsor	Contracts Team	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	UHL Sponsor	R&IDCOO / Contracts Team	Ensure Third Party Agreements are appropriately filed

5. Who Guideline Applies To

5.1 This guideline applies to all staff within UHL and external to UHL who are delivering research at Leicester's Hospitals.

6. Guideline Standards and Procedures

6.1 The SOP is detailed so the process can be clearly followed. Flowchart can be found within Appendix 1.

7. Education and Training

7.1 None.

8. Monitoring and Audit Criteria

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 approached according to research activity.	R&IDCOO

9. Supporting Documents and Key References

9.1 SOP S-1005 Appendix 1 & 2

10. Key Words

10.1 Research, Innovation, EDGE, Contracts, Vendor, Agreements, Sponsor, Host, Data Protection, Atamis,

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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:** R&I Deputy Chief Operating Officer
Reviewed by:	R&I Governance Meeting	
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REVIEW RECORD

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
13/01/2014	2	R&D Management Meeting	Alignment to University process.
21/04/2015	3	R&I Management Meeting	Change of Logo & Office name
02/08/2016	4	CM, DW	Consistency check and addition of Appendices
13/02/2017	5	CM	Change of Logo
May, Sep 2018	6	CM, RP, DW, LW CCL	May 2018: Amend process to reflect use of EDGE and processing of contracts. Sep 2018: Updated logo
May 2020	7	LW DH DW	Updated – to include Associate Director as signatory. Wider clarification wording
Aug 2021	8	LW	Addition of appendix 2 the multi-centre check list, updated to new trust template
Aug 2022	9	LW CS DW	Update

DISTRIBUTION RECORD:

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