1. Introduction

This Standard Operating Procedure (SOP) describes the requirements to provide assurance that a robust process has been followed when responding to Expression of Interest (EOI), Feasibility or Site Selection requests for any research conducted within a Clinical Management Group (CMG), Clinical Specialty or Corporate Directorate at University Hospitals of Leicester NHS Trust (UHL).

Assurance is required to confirm that research can be delivered in accordance with a study protocol and appropriate contract or agreement / Statement of Activity & Schedule of Events.

2. Scope

This SOP applies to all staff and external individuals involved in any research activity **HOSTED** by UHL or where UHL is a research **SITE**. It also includes any research activity that is sponsored by the UHL however, these processes are captured as part of the sponsor review process and therefore there is no requirement to repeat the exercise.

3. Assessment of Capacity

In order to assess whether or not a specific specialty within the UHL have the capacity, & / or capability, or are prepared to accept a research study a formal and robust assessment must be completed. The result of the assessment will quickly ascertain whether or not a study can be delivered in accordance with the protocol and appropriate study agreement / Statement of Activity & Schedule of Events.

The process can be entirely managed through the EDGE Database should the Speciality / CMG wish to use this approach. The EDGE Database attributes and workflows will be completed and managed through the Study Support Officers / Ethics & Regulatory Affairs personnel within individual specialties / Clinical Management Groups or by R&I Personnel.

Often in non-commercial studies, there will be no Expression of Interest or Site Selection but each study must have a minimum feasibility assessment conducted. Information about the expectations of the study specific feasibility can be found in the supporting SOPs **SOP C-2006a UHL & SOP C-2007a UHL.**

3.1) Expression of Interest (EOI)

In most cases, EOIs will be received from commercial companies, although in some cases they will be received from non-commercial sponsors. At UHL it makes no difference whether the EOI is from a commercial or a non-commercial sponsor - the same process should be followed. The source of the EOI may be different depending on the origin. A flowchart which helps to describe the process can be found at Appendix 1.

All EOI's received from the CRN EM Study Support Service will be put onto the NIHR Portal, where all documentation can be found. This is checked on a daily basis by the UHL R&I Feasibility Team and logged accordingly. All EOI's received whether through the NHIR Portal or direct email are all discussed at a weekly EOI Panel meeting to determine the correct team that they should be directed to and all relevant information is then sent on to the teams or PI. All responses received either interested or declined should be sent back to RIFeasibility@uhl-tr.nhs.uk where these will be logged and responses sent back to sponsors accordingly. This

process must be followed so that we can log all EOI's coming through the Trust and try to limit any duplications. .

If the Principal Investigator (PI) is invited to answer an EOI, that has come directly to them from a Sponsor, it is essential that the Principal Investigator or Study Support Officer/Ethics & Regulatory Affairs Officer notifies the R&I Feasibility Team using RIFeasibility@uhl-tr.nhs.uk.

On receipt of an EOI, the R&I Feasibility Team will commence completion of the relevant attributes relating to the EOI. The EOI response will also be tracked through EDGE.

There are sometimes deadlines for responding to EOI's and these are accommodated where possible depending on the outcome of the EOI Panel Meeting.

3.2) Confidential Disclosure Agreements (CDAs)

Confidential Disclosure Agreements (CDAs) must be managed through the UHL R&I Office. It is not appropriate for individual study teams or Principal Investigators (PI) to sign CDAs on behalf of the Trust. This is the same for both commercial and non-commercial studies. On occasion, a flexible CDA will have been signed which covers all EOIs from a company or group of companies and individual study CDAs may not be required.

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

- Director of Research & Innovation
- Associate Director of Research & Innovation
- Deputy Director of Research and Innovation
- Head of Research Operations

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

3.3) Feasibility

Where a completed EOI has been returned to the Sponsor, the next stage is often receipt of a feasibility document although as previously stated, not all studies follow this path.

Many Sponsors have their own feasibility documentation which should be completed, but essentially the process is used to assess whether or not a study could be delivered in the UHL should the site be selected.

Where the R&I Study Support Service is to be utilised, appropriate feasibility documentation will be completed and returned to the Sponsor. The local process for tracking feasibility will be followed by either R&I Study Support Service personnel or UHL specialty Ethics & Regulatory Affairs personnel. The EDGE system will be used to track feasibilities and will be populated by relevant personnel.

It is essential that a robust feasibility is undertaken. Failure to undertake a robust feasibility may result in a failure to deliver a study. Where it is clear which support departments will be required to assist with the delivery of the study, they must be engaged with the feasibility process at the earliest possible opportunity.

Things to consider at feasibility include:

- Number of conflicting studies on same participant population
- Timescales required
- Archiving costs and facilities
- Availability of staff to deliver

- Existence of relevant equipment & space available for new
- Capacity of support departments
- Storage & Capacity in pharmacy
- Numbers of participants likely to be eligible (be conservative)
- Adequate funding
- Recruitment or follow-up at satellite sites (e.g. Alliance sites)

Negotiation with the Sponsor must begin at this stage specifically to discuss areas of concern but also to include:

- Costing
- Staff Time (where there are discrepancies)
- Logistics
- Storage
- Equipment
- Payment Schedules
- Screening Payments

Clarification of all queries must be obtained from the Sponsor. Ideally this will be coordinated by the Ethics & Regulatory Affairs personal within the specialty or via R&I Study Support Service personnel.

If it is immediately evident that a study is not possible, it may be necessary to respond to the Sponsor indicating that we are unable to deliver currently but would like to be considered in the future.

It makes no difference whether the study is commercial or non-commercial, adopted or not the existence of a robust feasibility is critical to the successful delivery of a study.

3.4) Site Selection

In accordance with national guidelines, the site selection date is described as the date on the Sponsor email received by the site providing the minimum defined documents to enable site to commence arrangement and/or confirmation of local capacity and capability as applicable representing that the site has been selected to take part in the study. Where the Sponsor is also the site, this is the date of the HRA initial assessment letter. Further information about the national metrics can be found here:

https://www.nihr.ac.uk/research-and-impact/nhs-research-performance/hra-approvals-and-nihr-metrics.htm

This date must be recorded in the RED Site Level within EDGE. This will be done by R&I Study Support Officers.

Notification that UHL has been selected as a site may come several months after feasibility has been completed. If a period of time has elapsed that has implications to the original feasibility assessment, it is essential that a revision of the feasibility is conducted and the sponsor notified.

Sponsors manage site selection in many different ways. It is important to note that site 'selection' is different to site 'initiation'.

A sponsor will notify the site that they have been chosen to deliver the research through a variety of ways, but when notification of selection has been received, it is essential that the support staff within the specialty are notified.

4. Responsibilities

	Responsibility	Undertaken by	Activity
1	PI/Delegated specialty personnel	PI/Delegated specialty personnel	Notify R&I Feasibility Officer that a new EOI has been received – Commence completion of EDGE
2	PI/Delegated speciality personnel	PI/Delegated speciality personnel	Respond to EOI copying in RIFeasibility@uhl-tr.nhs.uk within the timelines required
3	R&I Feasibility Officer / R&I Study Support Service	R&I Feasibility Officer / R&I Study Support Service	Complete tracking information within EDGE
4	PI/Delegated speciality personnel	PI/Delegated speciality personnel	Notify R&I Feasibility Officer that a new Feasibility has been received Commence / continue completion of EDGE
5	PI/Delegated speciality personnel	PI/Delegated speciality personnel	Respond to Feasibility copying in RIFeasibility@uhl-tr.nhs.uk within timelines required. Commence / continue completion of EDGE
6	R&I Feasibility Officer / R&I Study Support Team	R&I Feasibility Officer / R&I Study Support Team	Complete tracking information within EDGE
7	PI/Delegated speciality personnel	PI/Delegated speciality personnel	Notify RIFeasibility@uhl-tr.nhs.uk if the UHL is selected as a site
8	PI/Delegated speciality personnel	PI/Delegated speciality personnel	Commence completion of EDGE

5. Who Guideline Applies To

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

6. Education and Training

A flowchart is provided in SOP C-2006 Appendix 1.

7. Education and Training

None

8. Monitoring Compliance

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting arrangements
Sponsor Audit	Randomly chosen for audit	Carolyn Maloney	As and when	A report will be produced

9. Supporting Documents and Key References

SOP C-2006 Appendix 1

SOP C-2006a

SOP C-2007a

10. Key Words

Research, Innovation, EDGE, EOI, Feasibility, Site Selection

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**	

12.

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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:	UHL Research Management Meeting	
Approved by:	**Professor Nigel Brunskill**	**Date Approved:** 24/5/24

REVIEW RECORD

Date	Issue Number	Reviewed By	Description Of Changes (If Any)
September 2015	2	Carolyn Maloney	Changes made to reflect utilisation of the EDGE system
June 2016	3	CM, LW, AG, SA	Consistency checking.
December 2016	4	CM	Additions to Site Selection.
February 2017	5	CM	Update to Logo
February 2019	6	CM, LW	Revision to Site Selection, update in relation to national metrics, update to Logo and consistency check.
April 2021	7	DW	Changes made to reflect new EOI process. Updated to new trust template

DISTRIBUTION RECORD:

Date	Name	Dept	Received