1. Introduction

This Standard Operating Procedure (SOP) describes the process for managing Expressions of Interest (EOI), feasibility, and site selection for research hosted by University Hospitals of Leicester NHS Trust (UHL), by Clinical Management Groups (CMGs), Clinical Specialties or Corporate Directorates.

These processes provide the assurance required to confirm that research can be delivered in accordance with a study protocol, appropriate contract or agreement, Organisation Information Document (OID) and Schedule of Events Cost Attribution Template (SoECAT)/Schedule of Events.

2. Scope

This SOP applies to all staff conducting research hosted by UHL, where UHL is a research site. For research sponsored by UHL, these processes are captured separately as part of the sponsor review and sign off process.

3. Procedure

3.1 Expressions of Interest (EOI)

In most cases, EOIs will be received from commercial companies, although in some cases they can be received from non-commercial sponsors.

EOIs received from the Clinical research Network East Midlands (CRN EM) Study Support Service can be accessed from the NIHR Portal. This portal is checked on a daily basis by the UHL R&I Feasibility Team. EOIs can also be received directly via e-mail. If the Principal Investigator (PI) is invited to answer an EOI, that has come directly to them from a Sponsor, it is essential that they notify the R&I Feasibility Team using RIFeasibility@uhl-tr.nhs.uk.

Irrespective of the source of the EOI, the same process should be followed. A flowchart describing the process for managing EOIs is detailed in Appendix 1.

All EOIs are reviewed at a weekly EOI Panel meeting to identify the correct team to distribute to. Once sent to the correct delivery team and/or PI, the response on whether the EOI can be accepted or declined should be sent back to RIFeasibility@uhl-tr.nhs.uk. This is to enable the R&I Feasibility team to respond to sponsors accordingly.

All EOIs and responses are logged appropriately to monitor response rates and timelines, via Edge.

3.2 Confidential Disclosure Agreements (CDAs)

Confidential Disclosure Agreements (CDAs) are sometimes requested at the EOI or feasibility stage. These must be managed through the UHL R&I Office. It is not permitted 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 contracts must be signed by an authorised signatory.

3.3 Sponsor directed feasibility

Where a completed EOI has been returned to the Sponsor, many sponsors may then request completion of a feasibility form. This is to assess whether or not a study can be delivered at UHL, should UHL be selected as a site.

It is essential that a robust feasibility is undertaken by the research team setting up the trial. 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

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

3.4 Local feasibility

In the absence of an adequate sponsor directed feasibility, a robust local internal feasibility must be undertaken by the research team setting up the trial prior to accepting a LIP and commencing local capacity and capability.

A local feasibility form can be found in Appendix 2.

3.4 Site Selection

Once a sponsor is happy with the feasibility provided, or when UHL have completed a local internal feasibility, UHL can be formally selected as a site. In accordance with national guidelines, the site selection date is the date that the sponsor provides the minimum defined documents to enable the site to process confirmation of local capacity and capability. The minimum defined documents are referred to nationally as the Local Information Pack (LIP), defined on the IRAS website. Where the Sponsor is also the site, this is the date of the HRA initial assessment letter. **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.

It is important to only accept the LIP once UHL have conducted a robust feasibility and can confirm that the study can proceed to set up and commence local confirmation of capacity and capability. The LIP can therefore be rejected if UHL is not able to confirm that the study will proceed to set up. The LIP can also be rejected if there are documents missing that are required to confirm local capacity and capability.

4. Education and Training

None

5. Supporting Documents and Key References

SOP C-2006 Appendix 1

SOP C-2006 Appendix 2

6. Key Words

Research, Innovation, EDGE, Expressions of Interest, Feasibility, Site Selection

This line signifies the end of the document

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 R&I Governance Meeting	

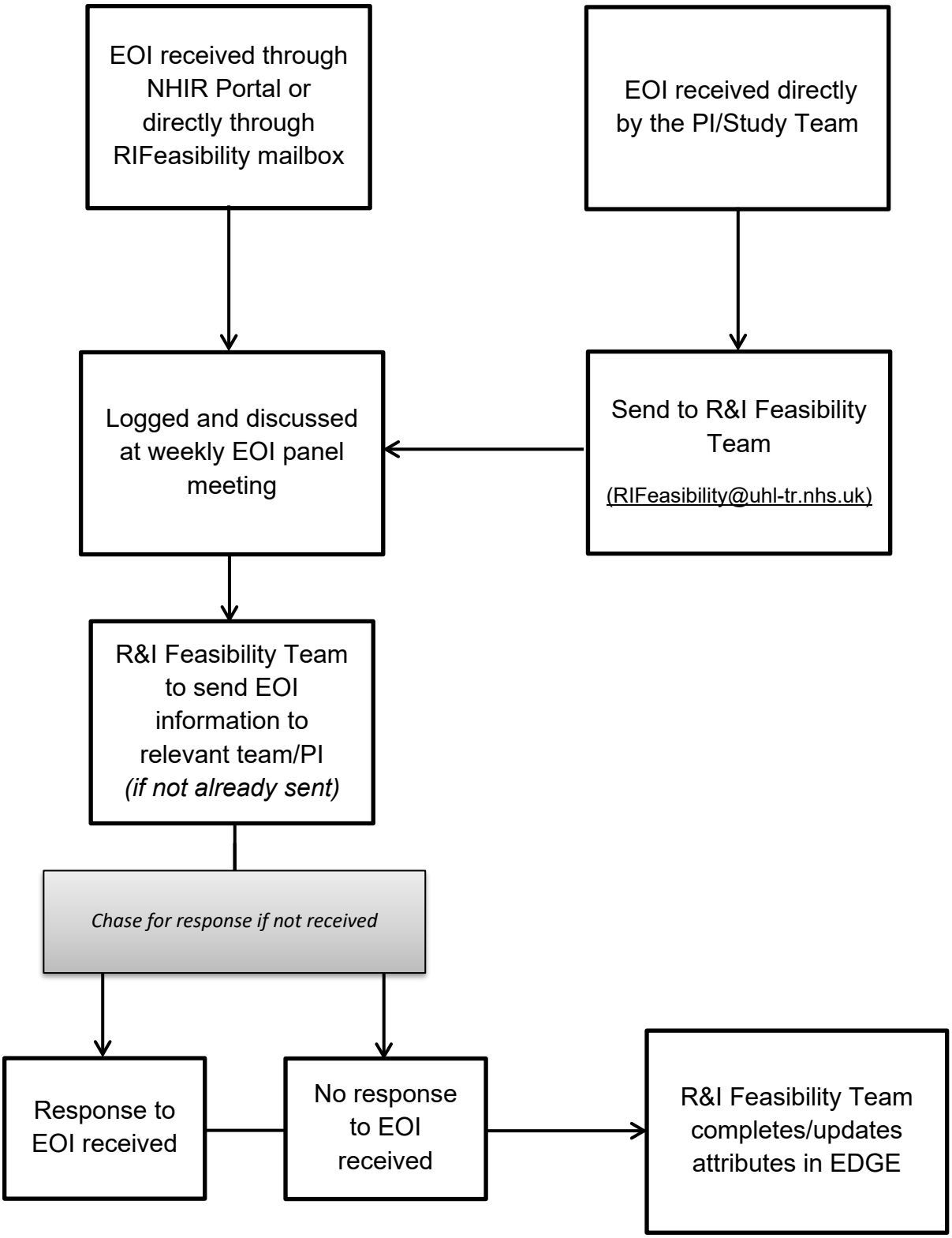
Approved by:	Professor Nigel Brunskill	Date Approved: 18.8.23 – Policy and Guideline Committee

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	LW	Changes made to reflect new EOI process. Updated to new trust template.
May 2023	8	LW/JB	Full review and update, to incorporate site selection and acceptance of LIP, in addition to a process for local feasibility.

DISTRIBUTION RECORD:			
Date	**Name**	**Dept**	**Received**

Expression of Interest, Feasibility and Site Selection Process Flowchart

SOP C-2006 - Appendix 1



University Hospitals of Leicester NHS Trust

FEASIBILITY ASSESSMENT FORM

Background information		**Feasibility Meeting information**	
Study title:		Date of meeting:	
EDGE number:		Meeting conducted by:	
NIHR portfolio study?	Yes No	Meeting attendees:	
• If YES, CRN Speciality:			
Commercial or non-commercial?		Protocol reviewed:	Version: Date:
Phase:		**Key Study Dates**	
CTIMP, non-CTIMP, ATMP or device?		Proposed study open to recruitment date:	
Sponsor:		Proposed site open to recruitment date:	
Chief Investigator:		Proposed study end of recruitment date:	
Key contacts: • R&I • Pharmacy • Labs • Imaging • Study Monitor/ CRA/ Trial Manager • Recruitment Contact		Recruitment period duration (locally):	

FUNDING	Response	Actions
Funder:		
Funding/budget details:		
• Is there adequate funding to run the trial?		
• Are patient expenses included/ considered?		
• Are screen failures funded?		
• Is CRF fees/support service fees included if required?		
• Is Chief Investigator fee included if required?		
• Is Site Initiation Visit fee included if required?		
• Have monitoring costs been included if local monitoring at UHL is required?		

STAFFING	Response	Actions
Is there adequate PI oversight?		
What staff/support is needed to deliver the study?		
• Is there capacity to support this with appropriately trained/		

knowledgeable staff?		
• Is any reception/admin support required?		
PATIENTS	**Response**	**Actions**
What patient population is required?		
Are there any competing/conflicting studies? If yes, how will this affect recruitment and can this be mitigated against?		
Is the inclusion/exclusion criteria appropriate for the population/participants?		
What is the local study recruitment target (per week/month/year?)		
Are there potentially enough eligible patients to meet this recruitment target?		
How and where will participants be identified, and who will do this?		
How does the protocol pathway compare to the standard of care pathway?		
• Are participants likely to be available to attend study visits (if additional to standard care)?		

• Are participants likely to be available to attend support services procedures e.g. imaging?		
Where will study visits take place?		
• What is the room availability like?		
• Is an application or approval required to use the room?		
Are any overnight stays required?		
• Are beds available for this?		
Are there any transport arrangements required for study visits?		
What consumables are required?		
Is any specialist equipment required?		
• What calibration and/or accreditation is needed for them?		

SUPPORT SERVICES	Response	Actions
Which support services are required?		
CTIMP studies- have pharmacy been notified?		
• Where will the study treatment be stored?		
• Are pharmacy available for dispensing (including satellite units)?		
Is there in-house lab availability?		
Are research samples being stored for future use? If yes, storage needs to be agreed and arranged		
Outcome		
Is the study feasible?	Yes No Further clarification needed	
Name of person leading feasibility assessment		