1. Introduction

This Standard Operating Procedure (SOP) describes the requirements to provide assurance that a robust review has been conducted within an individual Specialty area, Clinical Management Group (CMG), or Directorate, and appropriate registration on the EDGE database, is confirmed when responding to Expressions of Interest (EOI), Feasibilities, Capabilities or Site Selection requests for any research within University Hospitals of Leicester NHS Trust (UHL). The SOP assists with clarifying the process for 'Assessing' research capability in line with the Health Research Authority processes.

This SOP is provided as a ***recommended*** process to be utilised by each Specialty. The aim is to assist with the facilitation of internal processes required for authorisation of research at UHL.

2. Scope

This SOP applies to all 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 Process

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 an Assessment Process should be completed. The result will quickly ascertain whether or not a study can be delivered in accordance with the Protocol and appropriate study agreement / Organisation Information Document (OID & Schedule of Events costing Attribution Template (SOECAT).

The assessment process can be separated into TWO sections:

- Section 1: Expression of Interest (EOI), Feasibility, Capability and Site Selection – equivalent of 'Assess' for HRA

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- Section 2: Capability Assessment – equivalent of 'Accept' for HRA. This is covered in SOP C-2007 UHL.

Often in non-commercial studies, there will be no Section 1, but all studies will require the Section 2 Protocol & Contract Review & acceptance.

This SOP deals specifically with Section 1

4. Assess Process

4.1) Expressions of Interest (EOI) / Capabilities

In most cases, EOIs / Capability 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 / Capability 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 from the study team/PI will be discussed at a weekly EOI Panel meeting if applicable. All responses received back 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 / CAPABILITY, that has come directly to them or through the speciality, it is essential that as soon as it is possible, a notification is sent by email to RIFeasibility@uhl-tr.nhs.uk so that this can be logged accordingly. When responding back to an EOI / CAPABILITY it is essential that RIFeasibility@uhl-tr.nhs.uk is copied into responses. The R&I Feasibility Team will then ensure that the EOI / CAPABILITY has been added to the EDGE system if there is enough information to be added.

Each EOI / CAPABILITY is unique and it should be answered as an individual document. It is essential to identify the correct potential PI, which must be done first. The PI will be required to complete parts of the EOI / CAPABILITY within a time frame dictated by the sponsor. Once completed by the PI, the EOI / CAPABILITY must be sent back to the UHL Study Support Officer or the Ethics & Regulatory Affairs personnel for their final completion, before sending back to the originator and the RIFeasibiloty@uhl-tr.nhs.uk copied in

There are sometimes deadlines for responding to EOI's and these are accommodated where possible.

4.2) 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 EOI / CAPABILITYs 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 authorised signatories for UHL:

- Director of Research & Innovation
- Assistant Director of Research & Innovation
- Head of Research Operations

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

4.3) Site Selection

Notification that UHL has been selected as a site may come several months after EOI / Capability has been completed. If a period of time has elapsed that has implications to the original initial assessment, it is essential that a revision 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. This must then be updated on EDGE.

4.4) Feasibility

Where a completed EOI / CAPABILITY 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 Specialty should UHL be selected.

Where the CRN EM Study Support Service is to be utilised, appropriate feasibility documentation will be completed and returned to the sponsor using this pathway.

The local process for tracking feasibility will be followed by either UHL Study Support Officers or 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.

It is recommended that in order to complete a robust feasibility a meeting is held with all interested parties to discuss the proposed research activity in detail. This meeting should be documented and templates can be provided on request to assist with facilitation.

It is often possible that the Sponsor may be present at the Feasibility discussion as it may form a part of the Site Selection Visit. As a result you may feel that it is appropriate for some sections to be completed when the Sponsor is not in attendance. It must be clear that the feasibility and site selection process is both an opportunity to 'sell' UHL as a fabulous place to conduct research, but not to be overly ambitious and compromise our ability to actually deliver.

5. Responsibilities

	Responsibility	Undertaken by	Activity
1	PI/Delegated specialty personnel	PI/Delegated specialty personnel	Notify R&I Feasibility Officer that a new EOI / CAPABILITY has been received – Commence completion of EDGE
2	PI/Delegated speciality personnel	PI/Delegated speciality personnel	Respond to EOI / CAPABILITY copying in RIFeasibility@uhl-tr.nhs.uk within the timelines required
3	R&I Feasibility Officer / CRN EM Study Support	R&I Feasibility Officer / CRN EM Study Support	Complete tracking information within EDGE
4	PI/Delegated speciality personnel	PI/Delegated speciality personnel	Notify R&D Feasibility Officer that a new Feasibility has been received
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 / CRN EM Study Support	R&I Feasibility Officer / CRN EM Study Support	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

6. Who Guideline Applies To

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

7. Education and Training

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

8. Education and Training

None

9. 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

10. Supporting Documents and Key References

SOP C-2006a Appendix 1

SOP C-2007

SOP C-2006

11. Key Words

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

12. 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**	

13.

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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

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