1. Introduction

This Standard Operating Procedure (SOP) describes the process used to confirm that the University Hospitals of Leicester NHS Trust (UHL) has the Capacity and Capability (C&C) to deliver a research study.

The Health Research Authority (HRA) approval brings together the assessment of governance and legal compliance and usually incorporates an independent NHS Research Ethics Committee (REC) approval. Local NHS Trusts are expected in addition to any regulatory approvals, to assess, arrange and confirm their capacity and capability to deliver the research study. Once this is complete, the local trust will issue local authorisation for the study to start, referred to as 'Confirmation of Capacity and Capability' (C&C).

2. Scope

This SOP applies to all staff conducting research that is hosted or sponsored by the University Hospitals of Leicester NHS Trust (UHL).

3. General Procedure

3.1 The process of confirming Capacity and Capability cannot begin until the Local Information Pack (LIP) is received from the Sponsor or Sponsor representative. The IRAS website contains detail on what constitutes the LIP.

3.2 On receipt of the LIP, the study must be added to Edge. It is important to avoid duplications of studies and ensure that the study is not already on Edge. Only an individual with Admin rights has the ability to set up new studies within the system.

3.3 Before formally accepting the LIP, a local feasibility must be undertaken as detailed in SOP C-2006 EOI, Feasibility and Site Selection, in order to confirm that the study can proceed to set up and confirmation of C&C.

3.4 All relevant Edge Forms and Workflows must be completed.

3.5 The Research Support Officer reviewing the study will identify all local support departments involved in the research study and request their approval, as per their local requirements. All support departments must have given their authorisation and the support department workflow must be complete prior to issuing confirmation of C&C.

3.6 The Research Support Officer will check there are no outstanding requirements detailed in the feasibility process that will affect the study from starting.

3.7 Curriculum Vitae (CVs) are required for all members of the research team and these need to be signed and dated within the last 3 years. These must be uploaded to Edge. The HRA template CV can be found here Investigators CV - Health Research Authority (hra.nhs.uk)

3.8 The Research Support Officer will check that all members of staff conducting research activities for the study will hold a substantive contract, honorary contract or letter of access.

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3.9 The Research Support Officer will seek R&I Finance approval utilising the applicable costing template.

3.10 The Research Support Officer will arrange for any contracting to be reviewed and approved by the R&I Contracts team.

3.11 All study documentation must be uploaded to Edge in real-time and prior to issuing Confirmation of Capacity & Capability.

3.12 The Research Support Officer will ensure that the research team have up to date training as per the R&I training SOP C-2005 UHL Training for staff in hosted research.

3.13 The Research Support Officer will ensure that the study has been NIHR portfolio adopted or that there is a valid reason for it not being adopted. If in doubt the RSO will discuss with the R&I Head of QA and Compliance.

4. Issuing Confirmation of Capacity & Capability

4.1 Once all of the points in section 3 of this SOP are complete, the Research Support officer sends the request for C&C to RIauthorisations@uhl-tr.nhs.uk.

4.2 C&C will then be issued by personnel authorised to do so;

- Director of R&I
- Deputy Director of R&I
- Associate Director of R&I
- Head of Research Operations
- R&I Manager

5. Responsibilities

	Responsibility	Undertaken by	Activity
1	R&I Corporate / Specialty Officers	R&I Corporate / Specialty Officers	Adding new studies / requesting UHL has access to studies on EDGE and UHL is added as a site
2	R&I Corporate / Specialty Officers	R&I Corporate / Specialty Officers	Add and complete all relevant workflows / attributes
3	R&I Corporate / Specialty Officers	R&I Corporate / Specialty Officers	Ensure appropriate feasibility is complete for each study
4	R&I Corporate / Specialty Officers	R&I Corporate / Specialty Officers	Add all staff as relevant to each study. Confirm and upload CV's and training certificates including GCP / Consent etc
5	R&I Corporate / Specialty Officers	R&I Corporate / Specialty Officers	Notify corporate R&I of all staff without substantive or appropriate honorary contracts at UHL
6	R&I Corporate / Specialty Officers	R&I Corporate / Specialty Officers	Request confirmation of Capacity and Capability (C&C) from R&I Corporate vis RIauthorisations@uhl-tr.nhs.uk

	Responsibility	Undertaken by	Activity
7	R&I Corporate	R&I Corporate	Provide confirmation of C&C to Specialty, PI, Sponsor etc
8	R&I Corporate	R&I Corporate	Undertake appropriate QA checks for C&C confirmation

6. Supporting Documents and Key References

SOP C-2005 UHL Training for staff in hosted research.

7. Key Words

Research, Innovation, Capacity, Capability, Feasibility, Contract, C&C, CC

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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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