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 research studies.

1.1)

The process to achieve confirmation of C&C is delivered by appropriately trained and authorised personnel within individual clinical specialities or corporate directorates. The process outlined within this SOP was developed following a Listening into Action process in June / July 2019 where it was identified that duplication was causing unnecessary delays to the set up and confirmation process. The SOP version starts at V3 to accommodate some Appendices that have been in use prior to the development of this document.

1.2)

This SOP is dated February 2020, but full roll out of the new and revised process will be incremental with a view to including all research C&C assessments by end of June 2020.

2. Scope

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

3. Study Set Up

3.1 Adding a study to EDGE

Studies hosted by UHL come from many different sources. The process is identical for each study.

3.1.1)
Sources of studies can be from the following (not an exhaustive list):

- NIHR
- Pharma companies
- Researchers
- R&I admin
- R&I feasibility
- Universities
- Students
- Study teams

3.1.2)
When approached about a specific research study the individual with EDGE Administrator rights within the specialty should check to see if it is on EDGE. Only an individual with Admin rights has the ability to set up new studies within the system. The process to be followed is detailed in Appendix 1: Setting up a new study details the process for adding new studies to EDGE. Please follow this document to ensure all aspects are covered. Appendix 6 shows the process as a Flow Chart.

3.2 Administrator Rights in EDGE

Administrator rights will be provided to limited individuals within each specialty. That individual will be responsible for ensuring that studies are added appropriately and will assist Corporate R&I to add all relevant Attribute Lists and Workflows to the Green Level. They will be solely responsible for ensuring that all Attribute Lists and Workflows used by the speciality area are added and appropriately completed.

3.2.1)
Administrator rights within EDGE come with a set of responsibilities and undertakings. A declaration of understanding must be signed by each EDGE Administrator before undertaking the role. This declaration can be found at Appendix 3.

3.3 Site Feasibility

It is important that appropriate site feasibility is conducted. A generic feasibility form is attached in Appendix 2. This feasibility document can be adapted for each speciality. It is not a mandated process but it is strongly recommended and regularly contributes to the ease of delivery for studies.

3.3.1)
Confirmation that feasibility has been carried out should be recorded in the EDGE workflows.

3.3.2)
Sometimes feasibility is carried out well in advance of the study coming to fruition. It is therefore recommended as a minimum that a review of the feasibility is carried out if the work up of the study commences after six months has elapsed.

3.3.3)
Feasibilities are most productive when all aspects of the study are discussed. It is therefore important to ensure that all support departments are included in the discussions.

3.3.4)
The following is not an exhaustive list and the feasibility form should cover all relevant points (where generic form not used).

3.3.5)
Discussion points may include:

- Support departments required,
- Staff
- Finance
- Equipment
- Resources
- Regulatory approvals
- If UHL is added as a site in main application
- Access for those outside of UHL
- Contract requirements (including CI and PI agreements and service level agreements)
- Query data transfer
- Recruitment target
- Site type
- Timelines
- Amendments already made
- Review for novel interventions (New Interventional Procedures Authorisation Group) **
- Involvement of the LLR Alliance

3.4 Populating EDGE

It is important that all aspects of the study are reflected in EDGE. Using the documentation provided, ensure that all Entity Lists (Attributes) and relevant Workflows are completed.

3.4.1)
All Support Departments have an EDGE presence – it is important that the relevant departments are added and engaged in conversations at the earliest opportunity. The workflows provide detailed instructions which should always be followed. In addition, most Support Departments have their own 'Working Instruction' document in EDGE.

3.4.2)
A document detailing all Attribute Lists and Workflows are attached at Appendices 4 & 5.

3.4.3)
Ensure all documentation is uploaded to the RED level of EDGE including the completed feasibility document.

3.5 Finance Approval

Study teams will negotiate the costing templates (where provided) or the appropriate charging for procedures. Once completed, Finance Office within UHL Corporate R&I will provide the final finance approvals. There are no changes to this process as per SOP C-2019 UHL

3.6 Contract Negotiations

Contract negotiations and process have not changed. UHL Corporate R&I Contracts Office will process and negotiate all contracts as per SOP C-2012 UHL

3.7 Confirmation of Capacity and Capability request

Once all relevant workflows / attributes completed, all documents uploaded, all CV's, GCP and where appropriate Consent training has been confirmed and all relevant contracts for personnel confirmed confirmation of capacity and capability can be requested. This is confirmed by the completion of Workflow Request for CC&C which will be added to each study RED Level. Requests to be sent to RandIConfirmation@uhl-tr.nhs.uk using the template email.

4. Confirmation of Capacity & Capability

The individuals listed below are the only personnel at UHL who have the authority to provide Confirmation of Capacity and Capability:

4.1)

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

4.2)

The Confirmation of C&C Workflow will be populated. Only when all aspects can be confirmed will the confirmation be provided by email.

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	Complete appropriate feasibility 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	Specialty Officers	Specialty Officers	Notify corporate R&I of all staff without substantive or appropriate honorary contracts at UHL
6	Specialty Officers	Specialty Officers	Request confirmation of Capacity and Capability (C&C) from R&I Corporate
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

Appendices 1, 2, 3, 4, 5, 6

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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