1. Introduction

This Standard Operating Procedure (SOP) describes the process at the University Hospitals of Leicester NHS Trust (UHL) for giving 'authorisation' for research activity when the UHL are acting as a HOST organisation or research SITE and also includes authorisation where the UHL is the Sponsor.

The outcome of this SOP is that the UHL fulfils the requirements as a HOST Organisation or research SITE.

2. Scope

This SOP applies to all staff and external individuals involved in research activity HOSTED by UHL or where UHL is a research SITE.

3. Confirmation of Capability

In order to assess whether or not a specific specialty within the UHL will be able, or prepared to accept a research study feasibility process will be undertaken. The result of the feasibility will quickly ascertain whether or not a study can be delivered in accordance with the Protocol and appropriate study agreement. The feasibility process is covered in SOP C-2007 UHL Confirmation of Capability Assessment process for Research HOSTED by UHL.

4. Verification and Authorisation Process

When the study is originally added to EDGE, the system will generate a unique EDGE reference number. This reference number will be used to identify the study at all points during the life cycle of the research and will be used to identify the study when confirming authorisation to commence. Once all attributes and workflows have been completed for the study outlined in SOP C-2023 UHL and SOP C-2024 UHL an email must be sent to the relevant Study Support Officer within the R&I Office, unless they have been actively involved in the work up of the study. The Study Support Officer will review the entries in EDGE and once it has been confirmed that all are complete, the Head of Research Operations or their deputy will be notified.

Verification and confirmation that all relevant Attributes and Workflows have been completed will be conducted by the Head of Research Operations or their deputy.

4.1 Verification Process

All relevant Attributes & Workflows will be verified and supporting evidence confirmed. Supporting evidence must include:

- Confirmed finance approval and agreed costing for study activity
- Agreed contracts or appropriate agreements
- Approval of collaborating specialty areas

It may also include:

- Pharmacy approval
- Radiology/radiography approval (inc. Ultrasound)

- Laboratories approval
- Medical physics approval
- Nuclear medicine approval
- Audiology approval
- Ophthalmology approval
- Respiratory approval
- Cardiology approval
- Dentistry / orthodontics approval
- Medical illustration approval

The verification process will be completed within three (3) calendar days following receipt notification. Completion of the verification process will be confirmed by an authorisation email. Authorisation Attributes and Workflows may be completed only by:

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

Where UHL is acting as Sponsor as well as a HOST or SITE, it is expected that feasibility will be completed as part of the Sponsor review process which will then be fed into the Verification & Authorisation process.

4.2 Patient Identification Centres

It is recognised that where the UHL is asked to act as a Patient Identification Centre the full feasibility will not be required. It is however important to acknowledge that acting as a PIC still has resource implications and these must be recognised and reimbursed appropriately.

5. Authorisation Process

5.1 Authorised Signatories

Authorisation for research activity to commence at UHL will be confirmed by R&I by email. Authorised signatories for email confirmation by UHL are:

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

Emails must originate from one or other of the above email boxes. Any emails originating from other individuals will not be valid.

Contracts and Agreements must be directed to Contracts & Innovation manager through RIContract Mailbox RIContract@uhl-tr.nhs.uk. Once finalised these can be signed in accordance with the Contracts SOP C-2012 UHL.

It is important to be aware that the UHL signature on contracts represents confirmation of our capacity and capability. Therefore the contract must be signed as close to the date of authorisation email if not on the same day.

5.2 Confirmation of Authorisation

Authorisation confirmation will be provided by email within three (3) calendar days of notification that a study is ready for authorisation.

Authorisation confirms that UHL is able to deliver the research study in accordance with the approved Protocol and appropriate study agreements. The Authorisation will be confirmed as follows:

- Full Authorisation – no caveats or conditions required
- Partial Authorisation – with caveats or conditions

5.2.1 Full Authorisation

UHL is able to confirm ability to deliver the study in accordance with the protocol and appropriate study agreements. It is considered that UHL is ready to commence study related activity and allow Site Initiation to be undertaken. There is no requirement for any conditions to be set nor any caveats to be agreed.

5.2.2 Partial Authorisation

It is recognised that on some occasions a Partial Authorisation will be required to allow parts of a research study to commence before the Trust is ready or able to deliver the whole protocol. There are many and varied reasons where this may be necessary, and a pragmatic solution should be sought in collaboration with the Sponsor where ever possible. Examples include:

- Some of the study team (other than the PI) require training specific to the protocol and it has been difficult to organise but some have done it so are able to begin recruitment

- Or a piece of equipment may be required at a later time point, and where it is not required at the same time as the first recruited participant, flexibility is possible

It is expected that a Partial Authorisation letter will be followed up with a Full Authorisation letter when it is appropriate. Written confirmation that the caveats or conditions have been resolved or met will be required by the R&I before Full Authorisation is confirmed.

6. Responsibilities

	Responsibility	Undertaken by	Activity
1	PI/Delegated specialty personnel	PI/Delegated specialty personnel	Work up feasibility using SOP C-2007a UHL and submit to R&I office
2	R&I Office	R&I Office	Complete Verification process within three calendar days of receipt of notification
4	R&I Office	R&I Office	Complete Authorisation

7. Who Guideline Applies To

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

8. Education and Training

The SOP is detailed so the process can be clearly followed. No flowchart is provided / required.

9. Education and Training

None

10. 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

11. Supporting Documents and Key References

SOP C-2007

SOP C-2012

SOP C-2023

SOP C-2024

12. Key Words

Research, Innovation, Studies, Trials, EDGE, MHRA, ICH GCP, Authorisation, C&C, Capacity, Capability, PIC

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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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Author / Lead Officer:	Carolyn Maloney	**Job Title:** Head of Research Operations
Reviewed by:	R&I Governance Meeting	
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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, SA, AG	Changes to reflect developed process utilising the EDGE system
February 2017	4	CM	Update to Logo.
February 2019	5	CM, LW	Consistency check. Amendment from CA to feasibility, Update to Logo
February 2021	6	CM LW JJ	Update and consistency check, Reformatted to new template
April 2021	8	CM LW JJ	Update to new trust template
Sept 2021	9	LW	Review and update

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