1. Introduction

This Standard Operating Procedure (SOP) describes the process required to provide adequate assurance that an individual specialty within a Clinical Management Group (CMG) can deliver a research study in accordance with the approved Protocol and appropriate contract or agreement / Organisation Information Document (OID) & Schedule of Events Cost Attribution Template (SOECAT).

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. Confirmation of Capacity & Capability

In order to assess whether or not a specific specialty within the UHL have the capacity, capability, or are prepared to accept a research study a feasibility should be undertaken that will quickly ascertain whether or not a study can be delivered in accordance with the Protocol and appropriate study agreement / State Organisation Information Document (OID) & Schedule of Events Cost Attribution Template (SOECAT). In some circumstances the feasibility process will have been partially completed as part of an Expression of Interest (EOI), Site Feasibility or Site Selection Process. These processes are covered in the **SOP C – 2006(a) UHL EoI, Feasibility and Selection Process.**

In theory, the processes outlined in SOP C-2006 & C-2006a UHL will have in principle identified whether or not; it is possible for the specialty to deliver the study. It is however recognised that not all research sponsors require a formal Site Selection or Feasibility process prior to acceptance of a study. It is for this reason that speciality Feasibility is undertaken.

3.1) Confirmation of Capability & Assessment

The feasibility process must be documented in order to provide assurance to the CMG, specialty and the Research & Innovation Office (R&I) that the proposed research can be delivered by the specialty at UHL. Feasibility must be completed as comprehensively as possible. Where a Sponsor or Specialty feasibility is not available, a template provided at Appendix 1 could be used.

It is expected that the feasibility will be completed by personnel within the specific specialty or CMG with appropriate working knowledge. Ideally these personnel will be the Ethics & Regulatory Affairs type roles within the specialty but may also be the Study Support Officer for the individual specialty. It is expected that communication about the research will flow from the specialty / CMG through these personnel up to the R&I and vice versa.

4. Responsibilities

	Responsibility	Undertaken by	Activity
1	PI/Delegated specialty personnel	PI/Delegated specialty personnel	Work up a Valid feasibility

5. Who Guideline Applies To

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

6. Education and Training

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

7. Education and Training

None

8. 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

9. Supporting Documents and Key References

SOP C-2007 Appendix 1

SOP C-2006a

SOP C-2006

10. Key Words

Research, Innovation, EDGE, EOI, Feasibility, Capacity, Capability, SOECAT

11. 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**	

12.

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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.

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT		
Author / Lead Officer:	Carolyn Maloney	**Job Title:** Head of Research Operations
Reviewed by:	UHL Research Governance Meeting	
Approved by:	**Professor Nigel Brunskill**	**Date Approved:** 21/5/21

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	Removal of OCA and clarification of EDGE system process.
February 2017	4	CM	Update to Logos
February 2019	5	CM, LW	Focus on Feasibility process to provide confirmation of capacity in specialty area. Change of logo, consistency check.
February 2021	6	CM LW JJ	Update and consistency check, updated to new trust template

DISTRIBUTION RECORD:

Date	Name	Dept	Received