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.

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 1a 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. A copy will be securely stored in the main R&I Department shared M:Drive 'Researchshared//uhldata02'

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 Finance Approval **C279/2016.**

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 Study Contracts Management **C272/2016.**

3.7 Confirmation of Capacity and Capability (CC&C) 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. 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

7.Supporting Documents and Key References

SOP C-2023 Appendices 1a, 2, 3, 4, 5
SOP C-2019 UHL Finance Approval
SOP C-2012 UHL Study Contracts Management

8.Key Words

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

This line signifies the end of the document

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 R&I Governance Meeting	
Approved by:	Policy and Guideline Committee	**Date Approved: 23 July 2021**

REVIEW RECORD			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**
June 2023	V5	CM, MB	Updated to new template.

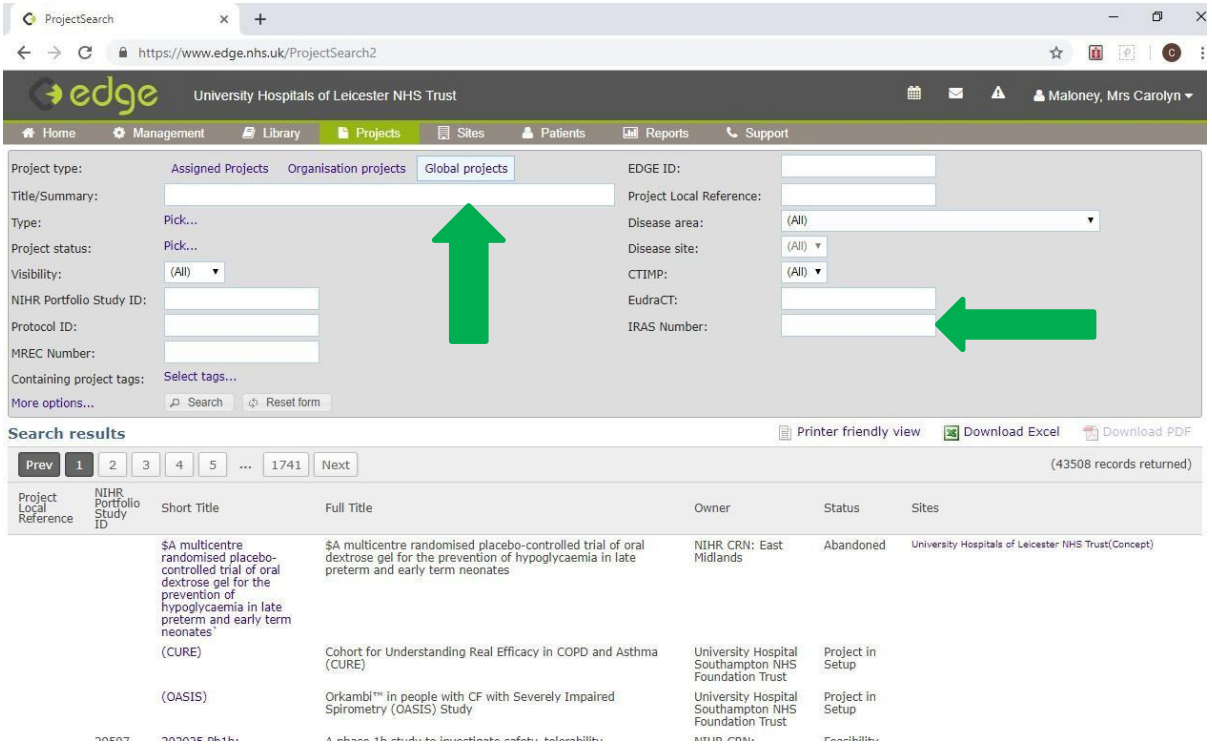
DISTRIBUTION RECORD:			
Date	**Name**	**Dept.**	**Received**

Appendix 1

Working Instructions for Adding UHL as a Site – Setting Up a New Study in EDGE

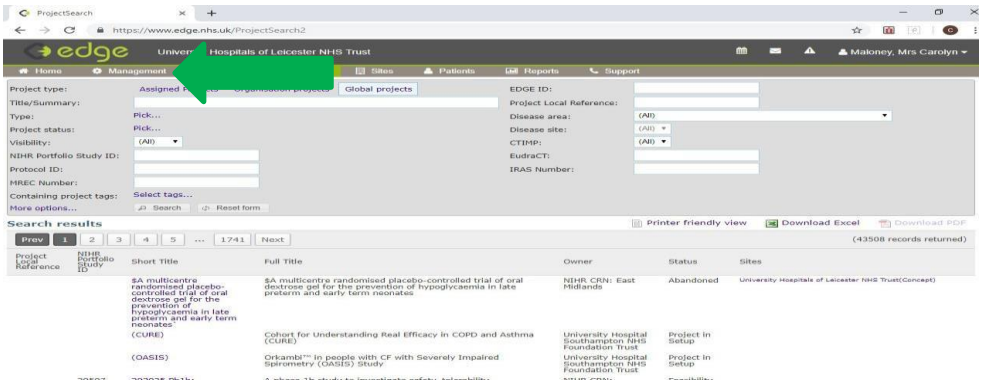
This working instruction is designed to be used by Administrator Users of EDGE where a study has not previously been added at Expression of Interest / Bids and Grants stage. Please see Working Instruction for EOI/Bids & Grants for detailed instructions in these cases. If you do not have Administrator access, please contact the R&I Office.

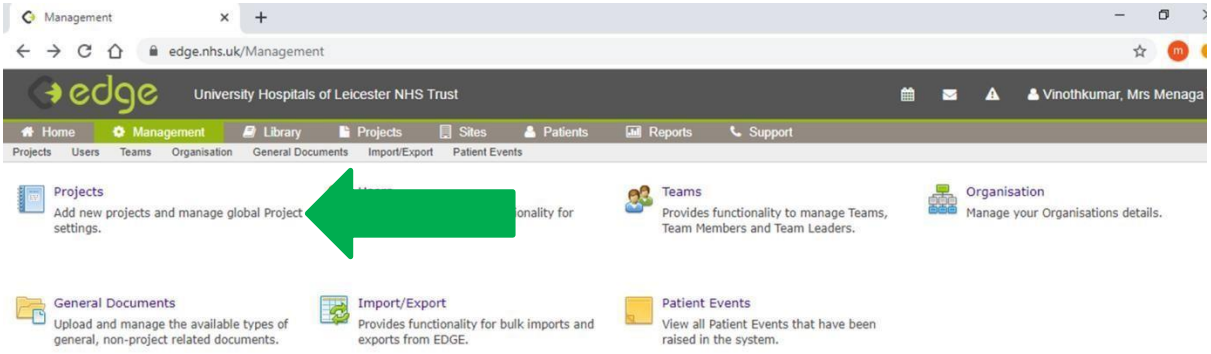
When a new study is received, EDGE must be searched thoroughly to ensure that the study is not already on the system. To do this, you need to perform a **GLOBAL** search with key words from the Project Title or use the reference numbers for the study. (IRAS/REC/Portfolio ID) Make sure you try more than one search before giving up. Sometimes it's also useful to search with the name of the PI. If you are unable to find the study using the FULL TITLE, try keywords from the title or the SHORT TITLE.

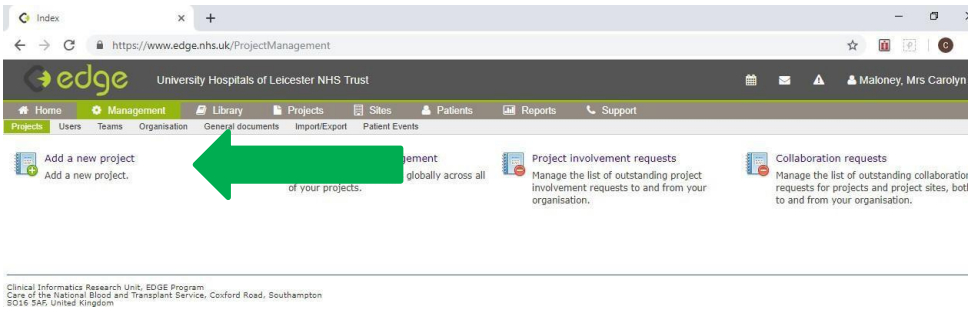


Where a study cannot be found on EDGE

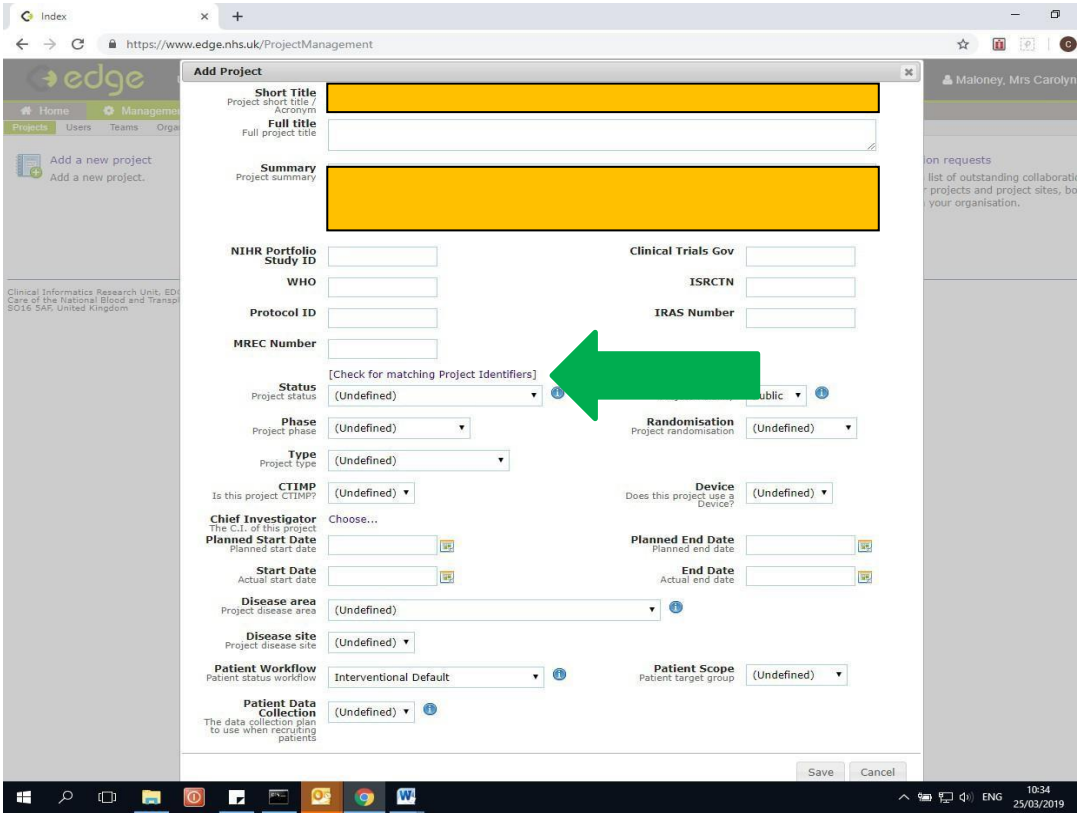
1. When the study cannot be found on EDGE, you need to create a new record. This can be done by clicking Management>Project>New Project.







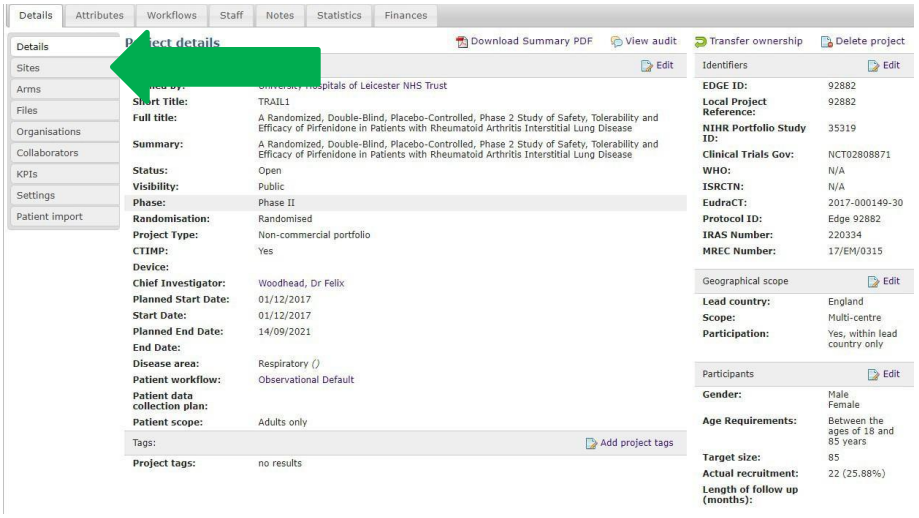
2. A set of fields will be presented to you which must be completed as far as is possible. This information should be available within the study information you have been provided



3. The highlighted fields are mandated. Please complete as much as possible on all tabs. If there are any fields that you are unsure about, please ask for help from you main contact in Corporate R&I.

4. Before pressing save, please check for duplicate studies. If a duplicate study has been found, please utilise this record. Do NOT generate a new study. If there are more than one duplicate of the same study, please contact UHL Data Team on RIData@uhl-tr.nhs.uk

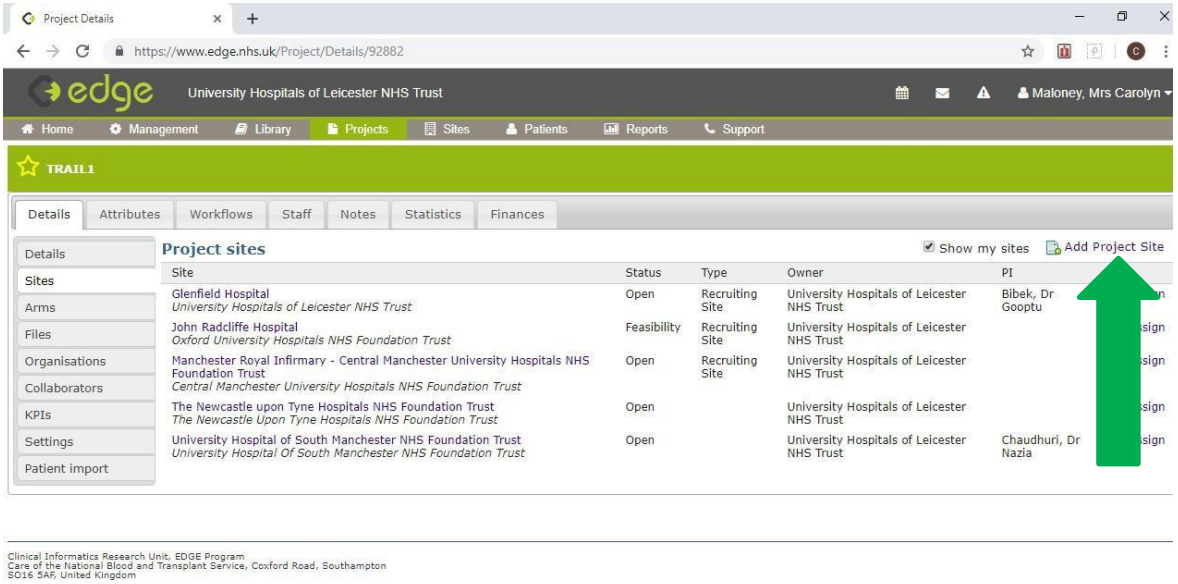
5. When you've completed the Green level front page, you need to add your site as a site i.e. Glenfield Hospital / Leicester Royal Infirmary or Leicester General Hospital. If you know the name of the Principal Investigator, and the specialty where they work, and the location of that specialty, please add the information in the RED level.



6. RED LEVEL: If you do not know the name of the Principal Investigator, add the relevant hospital as the site e.g. Glenfield, LRI / LGH, and leave the PI blank. The Support Officers will check the site and the PI when they start working the study up.

Study status on RED LEVEL.

The status must be set at 'Feasibility' while a study is going through the feasibility process. Once feasibility is complete the study status must be changed to 'Project Site in Set Up'.



Clinical Informatics Research Unit, EDGE Program
Care of the National Blood and Transplant Service, Coxford Road, Southampton
SO16 5AF, United Kingdom

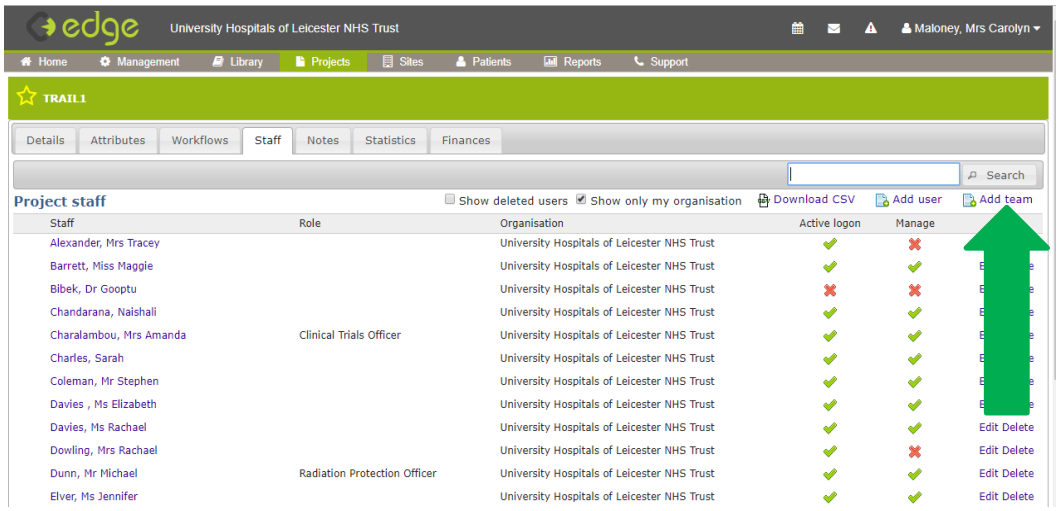
7. Once you have added the relevant UHL site, you must also add the following to the **GREEN** Level:

Teams:

UHL R&I TEAM

Speciality Team

When adding the Team please ensure that you tick Manage in the box



Study Support Teams must be added as follows:

Pharmacy: Where the study is a CTIMP

Medical Physics: Where the study is of a device - and / or if a device / piece of equipment is to be used as part of a study

Imaging: Where imaging is required as part of study (in IRAS filter page) – and/or where it's part of the study

Laboratories: Where samples are to be taken as part of the study (in IRAS filter page) – and / or where part of the study and UHL Pathology is involved

Nuclear Meds: Where Radiation Protection is ticked in IRAS

Radiation Protection: Where Radiation Protection is ticked in IRAS
All other Support Departments & Teams to be added by Study Support Officers

Attributes (Entities):

Contracts

Data Flows / GDPR

Finance Approval

Mandatory Category 1, 2, 3 & 4 (please complete Primary Clinical Management Area if known in Mandatory 1)

Software / Hardware requirements

Other attributes will be added as relevant when required. Attributes will be added by the Study support teams. Please see listings detailing completion responsibilities

Workflows

Archiving Arrangements

CMG Approval

Confirm Process Stage 3

Contracts Process (W.E.F 01/04/19)

Final Contracts Pre-Sign Checks (HRA Studies Only)

R&I Finance Approval

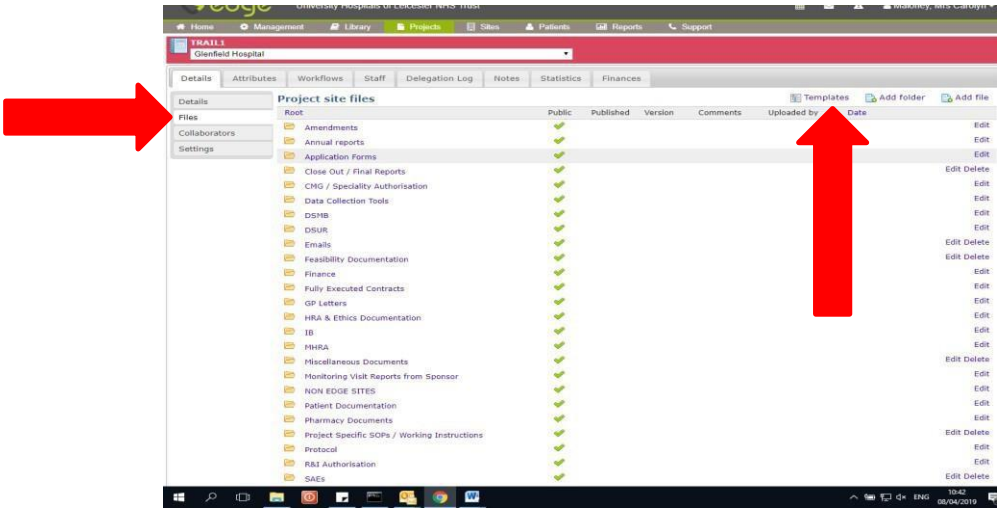
Study Staff Added

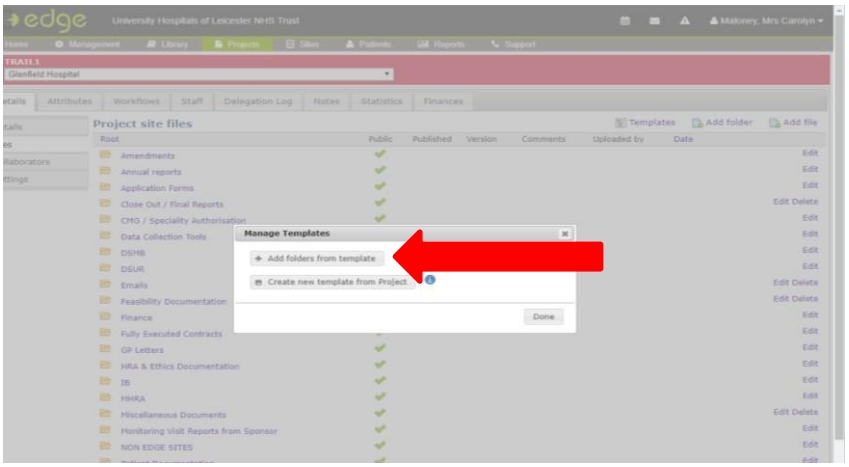
Other attributes will be added as relevant when required. Attributes will be added by the Study support teams. Please see listings detailing completion responsibilities

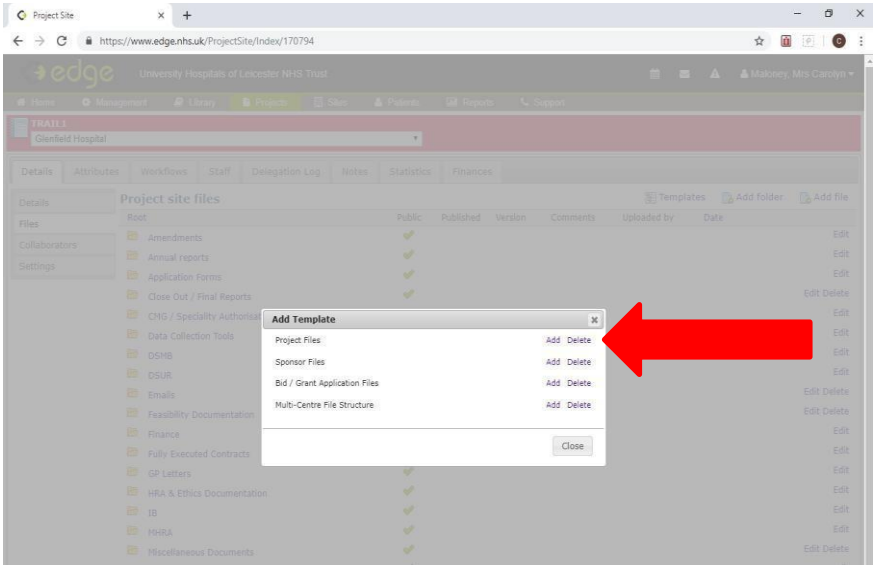
You add the relevant UHL site based on where the Primary Clinical Management Area resides within the trust, or the main base site of the P.I.

8. Once point 7 completed, you must add the following to the **RED** Level:

In Files you need to add the file structure template







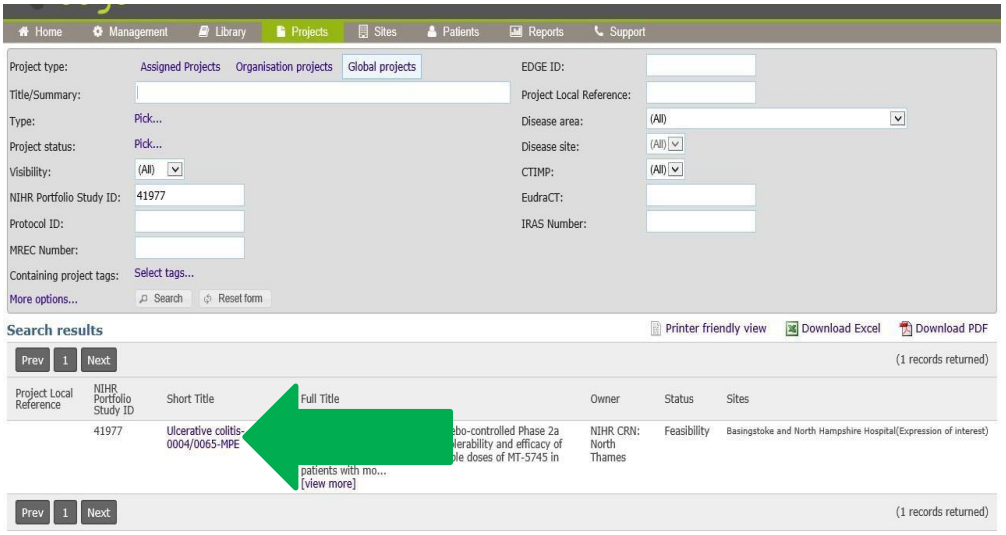
Upload any documentation you have received from your shared drives into the relevant EDGE Folder.

Where a project exists on EDGE

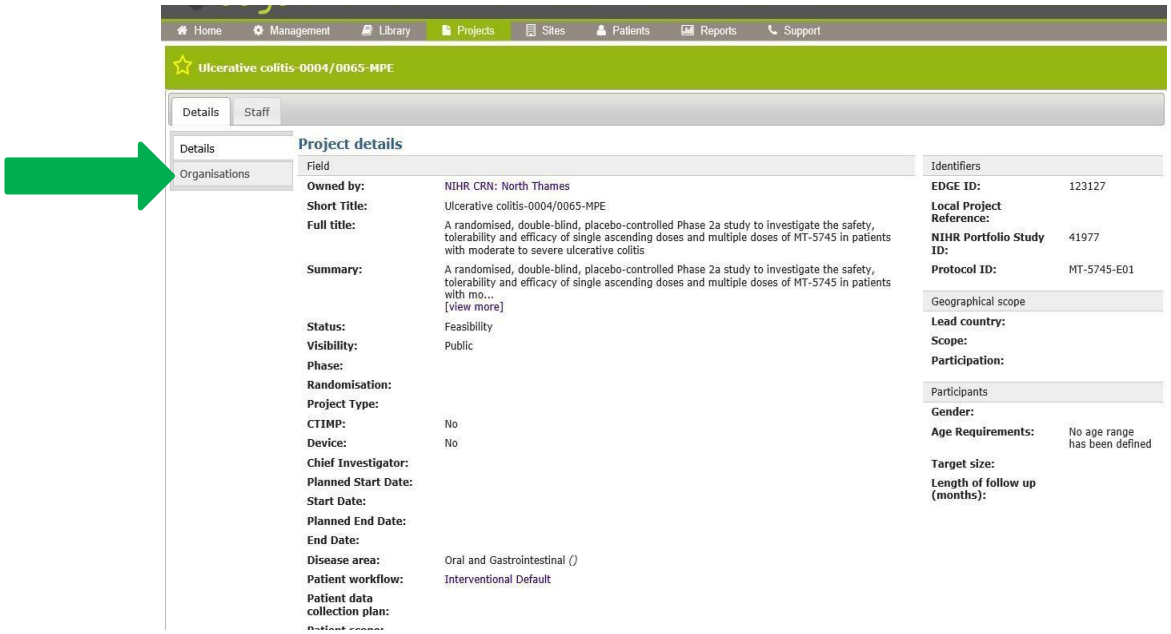
Where a project has already been added to EDGE, you need to request involvement for that study. Follow the screen shots below to show how to do this.

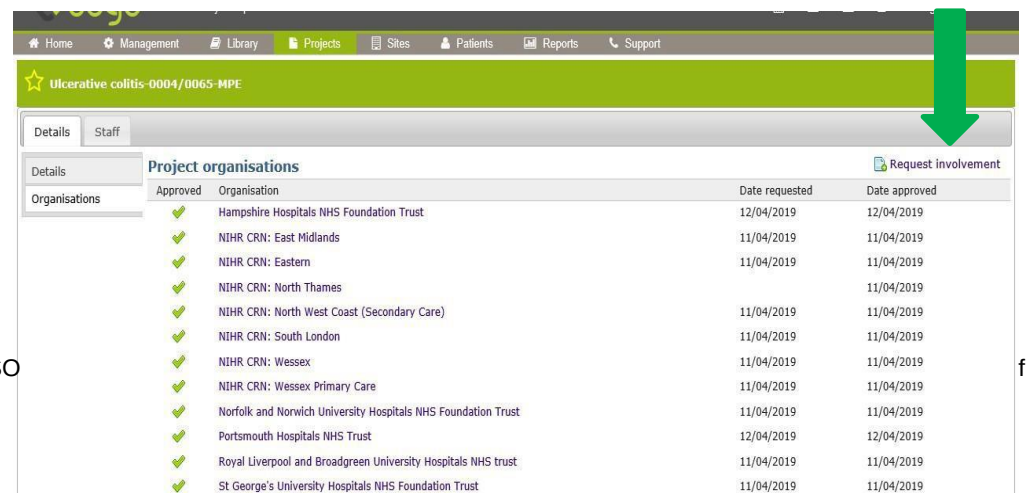
NB. You cannot add anything to the study until we have access to the record.

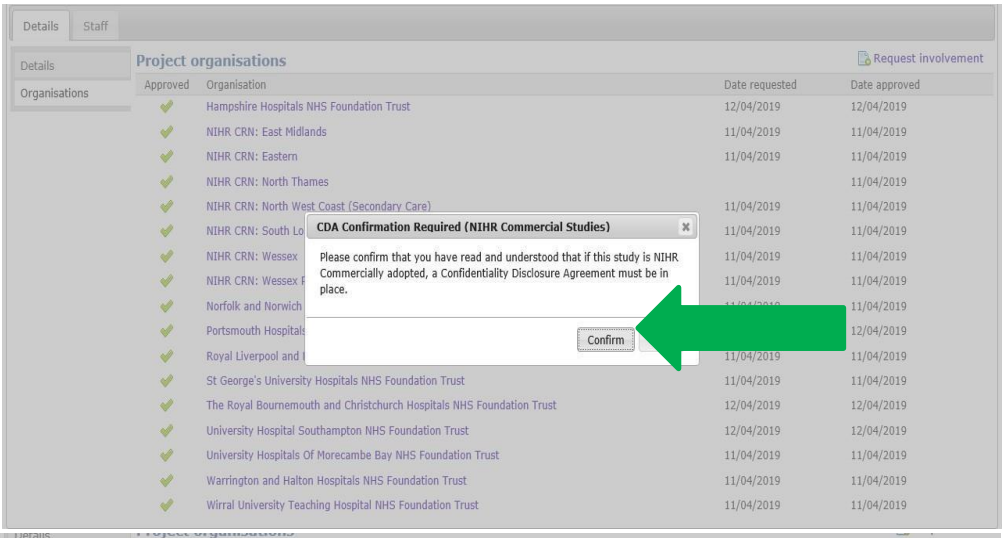
1. Click on the study link. That will take you through to the main project page in the GREEN level.



2. Click on Organisations and then click 'request involvement'. When asked if a CDA isin place, please click 'confirm'. A box asking about partner involvement will come up – please tick both boxes and click 'confirm'.






Details
Staff
Details
Organisations
Project organisations
Request involvement
Approved
Organisation
Date requested
Date approved
Hampshire Hospitals NHS Foundation Trust 12/04/2019 12/04/2019
NIHR CRN: East Midlands 11/04/2019 11/04/2019
NIHR CRN: Eastern 11/04/2019 11/04/2019
NIHR CRN: North Thames 11/04/2019
NIHR CRN: North West Coast (Secondary Care) 11/04/2019 11/04/2019
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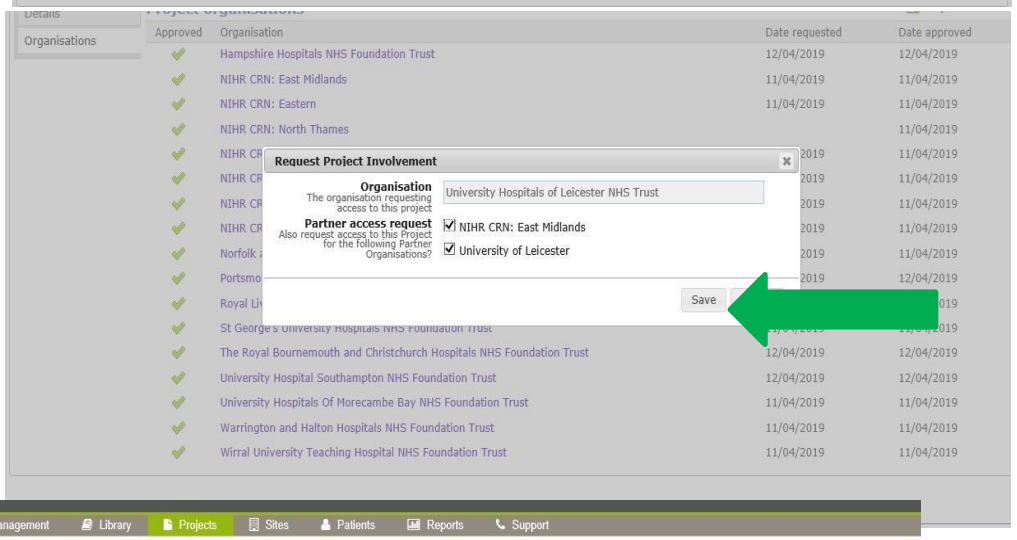
NIHR CRN: Wessex 11/04/2019 11/04/2019
NIHR CRN: Wessex F 11/04/2019 11/04/2019
Norfolk and Norwich 11/04/2019
Portsmouth Hospitals 12/04/2019
Royal Liverpool and 11/04/2019 11/04/2019
St George's University Hospitals NHS Foundation Trust 11/04/2019 11/04/2019
The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust 12/04/2019 12/04/2019
University Hospital Southampton NHS Foundation Trust 12/04/2019 12/04/2019
University Hospitals Of Morecambe Bay NHS Foundation Trust 11/04/2019 11/04/2019
Warrington and Halton Hospitals NHS Foundation Trust 11/04/2019 11/04/2019
Wirral University Teaching Hospital NHS Foundation Trust 11/04/2019 11/04/2019
CDA Confirmation Required (NIHR Commercial Studies)
Please confirm that you have read and understood that if this study is NIHR Commercially adopted, a Confidentiality Disclosure Agreement must be in place.
Confirm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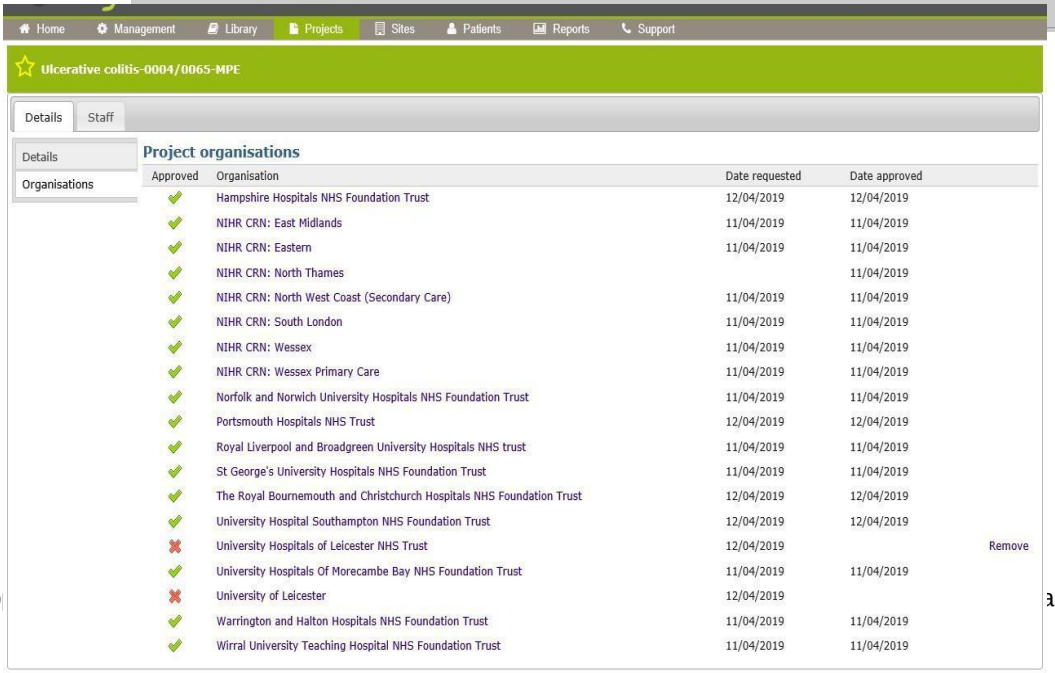
NIHR CRN: East Midlands 11/04/2019 11/04/2019
NIHR CRN: Eastern 11/04/2019 11/04/2019
NIHR CRN: North Thames 11/04/2019
Request Project Involvement
Organisation
The organisation requesting access to this project
University Hospitals of Leicester NHS Trust
Partner access request
Also request access to this Project for the following Partner Organisations?
NIHR CRN: East Midlands
University of Leicester
Save
The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust 12/04/2019 12/04/2019
University Hospital Southampton NHS Foundation Trust 12/04/2019 12/04/2019
University Hospitals Of Morecambe Bay NHS Foundation Trust 11/04/2019 11/04/2019
Warrington and Halton Hospitals NHS Foundation Trust 11/04/2019 11/04/2019
Wirral University Teaching Hospital NHS Foundation Trust 11/04/2019 11/04/2019


Home
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Reports
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Ulcerative colitis-0004/0065-MPE
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Staff
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Organisations
Project organisations
Approved
Organisation
Date requested
Date approved
Hampshire Hospitals NHS Foundation Trust 12/04/2019 12/04/2019
NIHR CRN: East Midlands 11/04/2019 11/04/2019
NIHR CRN: Eastern 11/04/2019 11/04/2019
NIHR CRN: North Thames 11/04/2019
NIHR CRN: North West Coast (Secondary Care) 11/04/2019 11/04/2019
NIHR CRN: South London 11/04/2019 11/04/2019
NIHR CRN: Wessex 11/04/2019 11/04/2019
NIHR CRN: Wessex Primary Care 11/04/2019 11/04/2019
Norfolk and Norwich University Hospitals NHS Foundation Trust 11/04/2019 11/04/2019
Portsmouth Hospitals NHS Trust 12/04/2019 12/04/2019
Royal Liverpool and Broadgreen University Hospitals NHS trust 11/04/2019 11/04/2019
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The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust 12/04/2019 12/04/2019
University Hospital Southampton NHS Foundation Trust 12/04/2019 12/04/2019
University Hospitals of Leicester NHS Trust 12/04/2019 Remove
University Hospitals Of Morecambe Bay NHS Foundation Trust 11/04/2019 11/04/2019
University of Leicester 12/04/2019
Warrington and Halton Hospitals NHS Foundation Trust 11/04/2019 11/04/2019
Wirral University Teaching Hospital NHS Foundation Trust 11/04/2019 11/04/2019

Make a note to check whether or not UHL has been added as a site. If it's been longer than 72 hours (3 days) email the EDGE administrators that own the record. To do this you need to go back into the study and click through to Organisations. If there is a green tick next to our name then you know we have access to the study.

To chase involvement you need to contact the owner of the record. This can found on the Green Level front page. Click into the hyperlink of the owner organisation and the EDGE Administrator for the owner will be displayed. Send them and email.

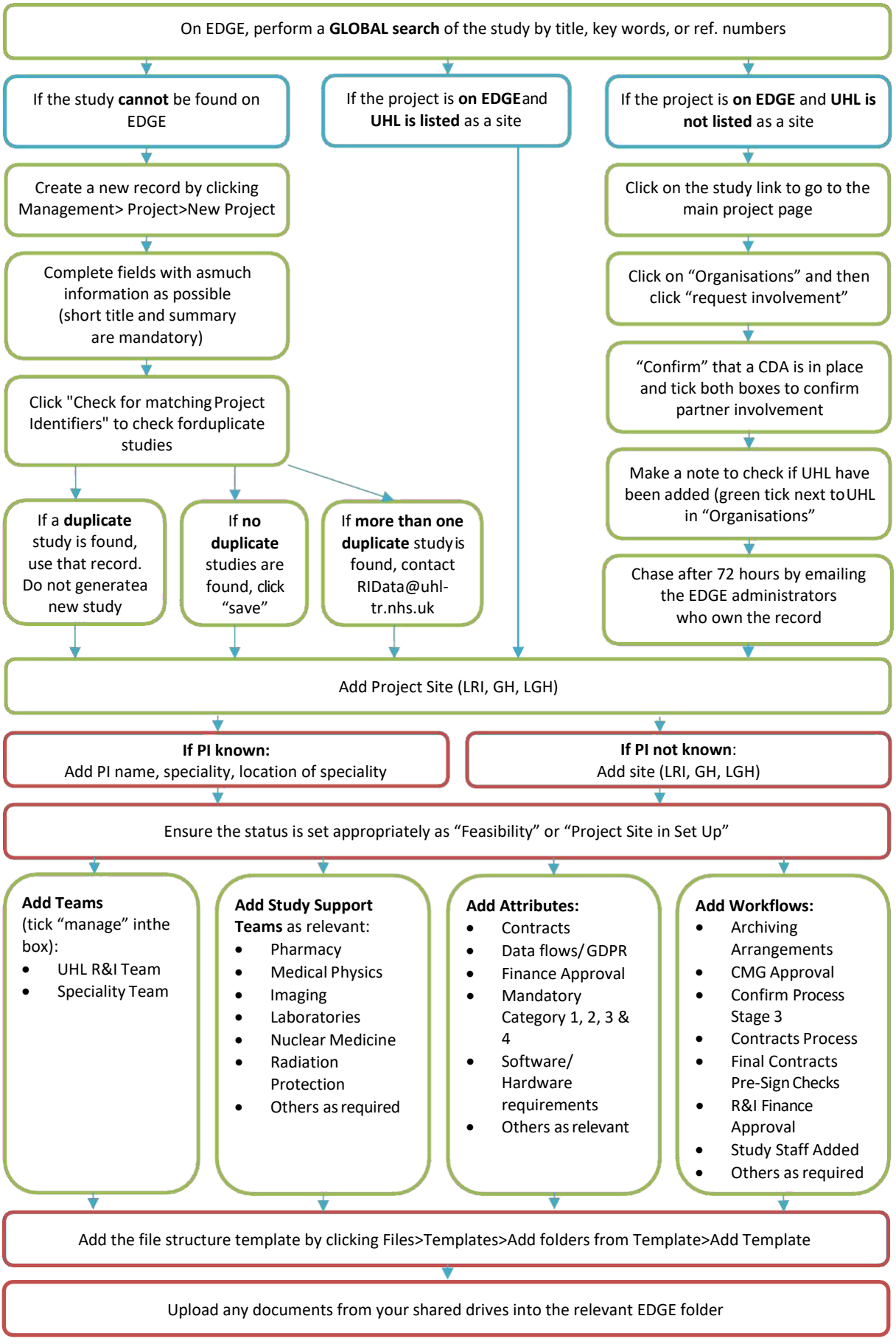
Once UHL request has been acknowledge, repeat as above from point 5 onwards

Where a project exists on EDGE and UHL has been added as a site

Follow the above instruction from Point 5 onwards.

Appendix 1a

FLOWCHART: Working Instructions for Adding UHL as a Site – Setting Up a New Study in EDGE



Appendix 2

FEASIBILITY ASSESSMENT FORM

Background information		**Feasibility Meeting information**	
Study title:		Date of meeting:	
Protocol reviewed:	Version: Date:	Meeting held:	Face to face Online/via email
EDGE number:		Meeting conducted by:	
IRAS number:		Meeting attendees:	
University reference number (if applicable):			
NIHR portfolio study?	Yes No	**Key Study Dates**	
• If YES, CRN Speciality:		Proposed study open to recruitment date:	
Commercial or non-commercial?		Proposed site open to recruitment date:	
Observational or Interventional?		Proposed study end of recruitment date:	
Phase:		Recruitment period duration (locally):	
CTIMP, non-CTIMP, ATMP or device?		Study treatment duration:	
Sponsor:		Study follow up duration:	
Chief Investigator:		Expected last patient last visit date:	

Funding		Key Contacts	
Funder:		R&I	
Funding/budget details:		Contracts	
• Are patient expenses included/ considered?		Pharmacy	
• Are screen failures funded (if so, is there a cap)?		Lab	
• Is CRF fee included/ required?		Imaging	
• Is Chief Investigator fee included/ required?		Other support departments (if applicable)	
• Is Site Initiation Visit fee included/ required?		Study Monitor/ CRA/ Trial Manager	
• Have monitoring costs been considered (if applicable)?		Recruitment Point Of Contact	

Questions to discuss with the CI/ PI/ Study Team			
Staffing	**Page no.**	**Responses**	**If further information/ action is required or the response can be mitigated, document in this column**
Principal Investigator:			
Co-Investigators:			
What staff/support is needed to			

deliver the study?			
• Is there capacity to support this with appropriately trained/ knowledgeable staff?			
Is any reception/admin support required?			

Patient Population and Targets	**Page no.**	**Responses**	**If further information/ action is required or the response can be mitigated, document in this column**
What patient population is required?			
Do any cohorts need to be considered?			
How many patients are seen per week/ month/ year with the condition?			
How many patients are seen per week/ month/ year who fit the inclusion/exclusion criteria?			
Is the inclusion/exclusion criteria appropriate for the population/participants?			
What is the patient's view of the study (medication, study visits, post-study access to IMP, etc.)?			
What is the overall study recruitment target (per week/month/year?)			

• What is the local recruitment target?			
• Can this be achieved?			

Patient Identification, Approach, Consent and Visits	**Page no.**	**Responses**	**If further information/ action is required or the response can be mitigated, document in this column**
How and where will participants be **identified**, and who will do this?			
How and when will participants be given **information**?			
Who will receive **informed consent** (ensure they are appropriately qualified/ trained)?			
How does the protocol pathway compare to the standard of care pathway?			
• Are participants likely to be available to attend study visits (if additional to standard care)?			
• Are participants likely to be available to attend support services procedures e.g. imaging?			
Where will study visits take place?			

• If within clinics, which day(s) are they held?			
• If outside of clinic, what is the room availability like?			
• Is an application or approval required to use the room?			
Are any overnight stays or out of hours visits/samples required?			
• Are beds/staff/facilities available for this?			
Who will book patients onto CRF Manager?			
Are there any transport arrangements required for study visits?			

Study Procedures, Treatment, and Equipment	**Page no.**	**Responses**			**If further information/ action is required or the response can be mitigated, document in this column**
Who will undertake the procedures at		**Procedure**	**Undertaken by?**	**Standard or Study?**	

each study visit (list as required)?					
Who will administer the study treatment/ intervention?					
What consumables are required?					
Is any specialist equipment required?					
• What calibration and accreditation is needed forthem?					

Support Services	**Page no.**	**Responses**	**If further information/ action is required or the response can be mitigated, document in this column**

Which support services are required?			
CTIMP studies- have pharmacy been notified?			
• Who funds/ supplies the IMP?			
• Where will the study treatment be stored?			
• Are pharmacy available for dispensing (including satellite units and out of hours)?			
• Is there any post-study access to the IMP?			
Is there in-house lab availability (consider processing, storage, shipment, and costs)?			
Are research samples being stored for future use (home grown-studies?) If YES, discuss arrangements.			

Administration	**Page no.**	**Responses**	**If further information/ action is required or the response can be mitigated, document in this column**
Who will set up the Case Report Form (for home-grown studies)?			

Who is going to design and maintain the database (for home-grown studies)?			
• Is funding available for this?			
Who will complete CPMS (if applicable)			
Who will complete the CRFs?			
Who will enter the data and answer data queries?			
Who will complete EDGE?			
Who will maintain the Site file/ Trial Master file?			
Who will meet with study monitors?			
• Have monitoring costs been considered (for home-grown or commercial studies)?			
What are the archiving arrangements (including funding)?			
Who will report AEs/ SAEs/SUSARs?			

• What is the likelihood of SAEs/AEs?			
Who will review SUSAR line listings?			

Governance	**Page no.**	**Responses**	**If further information/ action is required or the response can be mitigated, document in this column**
Has study received funding/ sponsor/ MHRA/REC/ HRA approval?			
Who is going to set up the study?			
Is NIPAG approval required (for new non-drug interventions)?			
Who is going to organise the Site Initiation Visit?			
Will there be an Investigator Meeting?			
• If YES, who will attend?			
Have all GDPR considerations for data storage and transfer been considered?			

Which internal speciality does the study come under?			
• Does the study fit within the speciality's strategy?			
Are there any competing/conflicting studies?			
• If YES, how will this affect recruitment?			
Are up to date CVs, GCPs, consent certificates, LoAs/RPs available for all key study staff?			
Is the study feasible?		Yes No Further clarification needed	

Signature:……

Name: ……

Date:……..

Appendix 3
EDGE Administrator Declaration of Understanding

EDGE Administrator access comes with a range of unique responsibilities. It provides unlimited access to all aspects of the University Hospitals Of Leicester NHS Trust EDGE Instance which has multiple uses and many of the Entity Lists (Attributes) and Workflows have been designed with specific speciality needs in mind.

You require EDGE Administrator access to be able to add Workflows, Entity Lists (Attributes), add GCP / Consent Training certificates and CV's to individuals within your specialties. These functions will enable you to facilitate the Capacity and Capability process within your specialty and you won't be 100% reliant on R&I Corporate adding things on your behalf.

Please read the following statements and initial where indicated:

No.	Statement	Initials
1,	I confirm that I understand the responsibilities that having EDGE Administrator rights provides.	
2.	I undertake that I will make no adjustments to Attributes / Workflows without gaining express written permission from Head of Research Operations.	
3.	I undertake that I will not provide any other individual with Administrator rights.	
4.	I undertake that I will add individuals to projects where they have legitimate access requirements.	
5.	I undertake as far as is possible to ensure that individuals who leave the Trust will be 'deleted' from the EDGE records and all access will be removed.	
6.	I undertake to discuss any additional workflows / attribute lists for my specialty before commencing a build in the system.	

Name:	
Speciality:	
Job Title:	
Signature:	

Appendix 4

List of Attributes - Responsibilities

List of All Attribute Lists			
	When to use	Who Adds to project	Who completes information
Alliance Involvement	When Alliance sites have been identified as being involved in the study - please see further information / guidance in General Documents	Specialty	Specialty
Bids / Grants Process Stage 1	To track Bids / Grants at Stage 1	Corporate R&I	Corporate R&I
Bids / Grants Process Stage 2	To track Bids / Grants at Stage 2	Corporate R&I	Corporate R&I
BRC / CLAHRC Involvement	Identifies specific areas of the CRF/BRC that are used on the study	Specialty	Specialty
Capacity/Capability Confirmation NOT REQUIRED	For use in studies where C&C is not required	Corporate R&I	Corporate R&I
COMMUNICATIONS	To track the involvement of Communications in the study	R&I Comms	R&I Comms
Contracts Attribute	To manage the study contracts	Corporate R&I	Corporate R&I
Data Driven Technologies - AI/APPs etc	To be added when AI / APPs are being used as part of the study	Specialty	Specialty
Data Flows / GDPR	EVERY STUDY	Corporate R&I	Corporate R&I with input from Speciality
EOI / Capability	Where an EOI is required	Corporate R&I	Corporate R&I with input from Speciality
Feasibility (Arrange)	Being phased out	N/A	N/A

Finance Approval	EVERY STUDY	Corporate R&I	Corporate R&I with input from Speciality
Laboratory Involvement - CTIMPS ONLY	Every study where Laboratories are involved - either UHL or External	Corporate R&I	Corporate R&I with input from Speciality
Laboratory Involvement - NON CTIMP	Every study where Laboratories are involved - either UHL or External	Corporate R&I	Corporate R&I with input from Speciality
Mandatory Category 1 (UHL)	EVERY STUDY	Corporate R&I	Corporate R&I
Mandatory Category 2 (UHL)	EVERY STUDY	Corporate R&I	Corporate R&I
Mandatory Category 3	EVERY STUDY	Corporate R&I	Corporate R&I
Mandatory Category 4 - Authorisation	EVERY STUDY	Corporate R&I	Corporate R&I
Medical Devices / Equipment	Every study where Medical Equipment / Devices are used in the study	Corporate R&I	Specialty
MHRA - UHL SPONSORED CTIMPS ONLY	UHL as SPONSOR - where relevant	Corporate R&I	Corporate R&I
Musketeers Memorandum Studies Approval	Added only for Musketeers studies	Corporate R&I	Corporate R&I with input from Speciality
Pandemic Study	Added only when Pandemic studies are woken up	Corporate R&I	Corporate R&I with input from Speciality
Partial to Full Authorisation	When partial C&C can be given ahead of full C&C	Corporate R&I	Corporate R&I with input from Speciality
Pharmacy Involvement	Added for every CTIMP	Corporate R&I	Corporate R&I with input from Speciality

Software / Hardware Requirements	Every study where software / hardware is required	Corporate R&I	Corporate R&I with input from Speciality
SPONSOR 1 APPLICATION PROCESS - Multi-Centre	UHL as SPONSOR - where relevant	Corporate R&I	Corporate R&I
SPONSOR 10 Monitoring Provision	UHL as SPONSOR - where relevant	Corporate R&I	Corporate R&I
SPONSOR 11 PIS / ICF Process	UHL as SPONSOR - where relevant	Corporate R&I	Corporate R&I
SPONSOR 12a - Research Risk Assessment (CtIMP)	UHL as SPONSOR - where relevant	Corporate R&I	Corporate R&I
SPONSOR 12b - Research Risk Assessment (Devices)	UHL as SPONSOR - where relevant	Corporate R&I	Corporate R&I
SPONSOR 12c - Research Risk Assessment	UHL as SPONSOR - where relevant	Corporate R&I	Corporate R&I
SPONSOR 13 HEALTHY VOLUNTEER STUDIES	UHL as SPONSOR - where relevant	Corporate R&I	Corporate R&I
SPONSOR 14 - REC Analysis	UHL as SPONSOR - where relevant	Corporate R&I	Corporate R&I
SPONSOR 15 End of Sponsor Green Light	UHL as SPONSOR - where relevant	Corporate R&I	Corporate R&I
SPONSOR 2 APPLICATION PROCESS - Single Centre	UHL as SPONSOR - where relevant	Corporate R&I	Corporate R&I
SPONSOR 3 CRF / Data Collection	UHL as SPONSOR - where relevant	Corporate R&I	Corporate R&I
SPONSOR 4 RANDOMISATION	UHL as SPONSOR - where relevant	Corporate R&I	Corporate R&I
SPONSOR 5 REVIEW - GENERAL	UHL as SPONSOR - where relevant	Corporate R&I	Corporate R&I
SPONSOR 6 REVIEW - QUESTIONNAIRES	UHL as SPONSOR - where relevant	Corporate R&I	Corporate R&I
SPONSOR 7 STATISTICS	UHL as SPONSOR - where relevant	Corporate R&I	Corporate R&I
SPONSOR 8 Final Study Publication/Report	UHL as SPONSOR - where relevant	Corporate R&I	Corporate R&I
SPONSOR 9 FINANCE APPROVAL	UHL as SPONSOR - where relevant	Corporate R&I	Corporate R&I
Study Suspension	Added when a study is suspended	Corporate R&I	Corporate R&I with input from Speciality

Appendix 5

Workflows - Responsibilities

Name of Workflow - GREEN to be added to PROJECT LEVEL. RED to be added to SITE LEVEL	What is the purpose	When must it be used	Who completes it?
Amendment Effective 01/04/19	To be added every time an amendment requires R&I Approval/Acknowledgement. This includes substantial and non-substantial amendments, regardless of Categorisation.	To be added every time an amendment requires R&I Approval/Acknowledgement. Substantial and Non Substantial Amendments	TBC
Antimicrobial Agent or Process	To identify Antimicrobial Agent or processes in use	This must be completed whenever it is identified that an Antimicrobial Agent or process is being used within the study & where the Attribute in Mandatory 1 has been ticked as 'YES'. The best individual to make the call will be a member of either the clinical team or pharmacy	Specialty Staff with liaison from Pharmacy
Archiving Arrangements	To track Archiving Arrangements	Every single study - in addition Mandatory Category 3 Attribute must be added	Corporate R&I
Audiology Approval	To facilitate Audiology approval	For every study where Audiology is required to deliver the study	Any staff facilitating Audiology Approval - Speciality Staff

Bid / Grant process - Lead Organisation	To track Bids / Grants	Every Bid / Grant. In addition the Bids & Grants Attribute must be added	Corporate R&I
Capacity / Capability Confirmation NOT REQUIRED	This workflow must be added to a study where there is no expectation for a formal acceptance of Capacity or Capability.		TBC
Cardiac Investigations	To be used by Cardiac Investigations & completed by authorised personnel within Cardiac Investigations. Marian Campton	This workflow is to be used when Cardiac Investigations are required for studies. The workflow must be completed by authorised individuals within Cardiac Investigations.	Cardiac Investigations Team Only
CMG Approval - CHUGGS	To manage the CMG / Speciality approval process	To be added where the Cancer, Haematology, Urology, Gastroenterology & General Surgery CMG have involvement in the study either as a primary or secondary CMG	Any staff facilitating CHUGGS CMG Approval - Speciality Team
CMG Approval - Corporate	To manage the CMG / Speciality approval process	To be added where the Corporate CMG have involvement in the study either as a primary or secondary CMG	Any staff facilitating Corporate CMG Approval - Speciality Team
CMG Approval - CSI	To manage the CMG / Speciality approval process	To be added where the Clinical Services CMG have involvement in the study either as a primary or secondary CMG. This is separate and different to where CSI is involved with Support Services / Departments - it relates to when the CI/PI or collaborators are leading the study	Any staff facilitating CSI CMG Approval - Speciality Team

CMG Approval - ED & Specialist Meds	To manage the CMG / Speciality approval process	To be added where the Emergency Department or one of Specialist Medicines CMG have involvement in the study either as a primary or secondary CMG	Any staff facilitating EDSM CMG Approval - Speciality Team
CMG Approval - ITAPS	To manage the CMG / Speciality approval process	To be added where the Intensive Care, Theatres, Anaesthesia, Sleep & Pain CMG have involvement in the study either as a primary or secondary CMG	Any staff facilitating ITAPS CMG Approval - Speciality Team
CMG Approval - MSK & Specialist Surgery	To manage the CMG / Speciality approval process	To be added where the Musculoskeletal & Specialist Surgery CMG have involvement in the study either as a primary or secondary CMG	Any staff facilitating MSK SS CMG Approval - Speciality Team
CMG Approval - RRCV	To manage the CMG / Speciality approval process	To be added where the Respiratory, Renal, Cardiac and Vascular CMG have involvement in the study either as a primary or secondary CMG	Any staff facilitating RRCV CMG Approval - Speciality Team
CMG Approval - Womens & Childrens	To manage the CMG / Speciality approval process	To be added where the Women's & Children's CMG have involvement in the study either as a primary or secondary CMG	Any staff facilitating Womens & Childrens CMG Approval - Speciality Team
Collaborations Confirmed - Multi Centre	This Workflow must be added to all Multi-centre studies to confirm that the sites are added as collaborators with UHL and vice versa. Where the study is on the Portfolio the CRNEM must also be added as a collaborator with each site too!		TBC

Confidentiality Disclosure Agreement Process	This is the workflow to use when processing a CDA for a prospective study / Expression of Interest or Capability. The CDA process is the same for any study.		Corporate R&I
Confirm process Stage 3 (R&I Authorisation)	To track the authorisation process for UHL R&I	Every single study. In addition Mandatory Category 4 must be added	Head of Research Operations, Deputy Dir R&I or R&I Manager only
Contract process	To track the progress of contracts	Every single study where a contract is required except for CDAs. In addition the Contracts Attribute must be addded	Corporate R&I
DSUR - SOP S-1004 UHL	To be completed for studies where a DSUR is due to be sent to regulatory authorities.		Corporate R&I
Final Contract Pre-sign Checks (HRA Only)	To check the final stages of Assess, Arrange, Confirm before Contract is signed	This workflow to be completed when the study has been processed through the HRA.	Corporate R&I
Imaging Approval	To be completed by Imaging - authorised signatory - Bruno Morgan	Provides Imaging authorisation confirmation for each study where Imaging is required	Imaging Staff Only
Imaging Post-Approval Check	To be completed by Imaging once approval of a study has been confirmed	To be completed by Imaging	Imaging Staff Only
Laboratory Services Approval	To faciliate Laboratory Services approval	For every study where Laboratory Services is required to deliver the study and where it is identifed in Mandatory Category 1 that Laboratory Services are required	Any staff facilitating study set up - Speciality Team

LCBRU Internal Authorisations Complete	To facilitate internal Leicester Cardiac BRU Processes	For every study where the LCBRU is involved	LCBRU Staff Only
Medical Illustration	To faciliate Medical Illustration approval	For every study where Medical Illustration is required to deliver the study and where it is identified in Mandatory Category 1 that Medical Illustration are required	Any staff facilitating study set up - Speciality Team
Medical Physics Approval	To facilitate Medical Physics approval	For every study where Medical Physics is required to deliver the study and where it is identified in Mandatory Category 1 that Medical Physics are required	Any staff facilitating study set up - Speciality Team
Musketeers Memorandum Studies Workflow	To facilitate MM studies process	For every study where MM is the Process to be followed	Corporate R&I
NOT YET IN USE UHL Pharmacy Set Up	To facilitate Pharmacy Set Up	For every study where Pharmacy is involved	Pharmacy Staff Only
Nuclear Medicine Approval	To facilitate Nuclear Medicine Approval	For every study where Nuclear Medicine is required to deliver the study and where it is identified in Mandatory Category 1 that Nuclear Medicine are required	Any staff facilitating study set up - Speciality Team
Opthalmology Approval	To facilitate Opthalmology Approval	For every study where Opthalmology is required to deliver the study and where it is identified in Mandatory Category 1 that Opthalmology are required	Any staff facilitating study set up - Speciality Team

Orthodontics	To faciliate Orthodontics approval	For every study where Orthodontics is required to deliver the study and where it is identified in Mandatory Category 1 that Orthodontics are required	Any staff facilitating study set up - Speciality Team
Pandemic Studies Annual Review	This workflow is to be used to check that all potential pandemic studies that could be launched at UHL are as ready as possible without actually hitting 'go'.		TBC
Pandemic Studies Hard Launch	This workflow is to be used when a pandemic has been declared.		TBC
Partial Authorisation Workflow	To track the progress of a study that was initially given Partial authorisation then progresses to Full Authorisation	Every study initially given Partial authorisation. In addition Partial to Full authorisation attribute must be added	Head of Research Operations, Deputy Dir R&I or R&I Manager only
R&I Finance Approval	To faciliate Finance approval	For every study	Corporate R&I
Recall from Archive	To be added to all studies along with Mandatory Category 3. Details that the Archiving Arrangements have been discussed with the Sponsor before the study commences.		Corporate R&I
Research Passport, NHS to NHS & H/C	To track the progress of Research Passport applications	Every time a HRC/letter of access is required. A workflow must be added for each individual - cloned and renamed accordingly	Speciality Team and Corporate R&I

Respiratory Services	To facilitate Respiratory Services Approval	For every study where Respiratory Services is required to deliver the study and where it is identified in Mandatory Category 1 that Respiratory Services are required	Any staff facilitating study set up - Speciality Team
SPONSOR 01 Initial Review No Risk Assessment	See SOP S-1003 UHL Appendix 4 to determine whether or not a Risk Assessment is required.		Corporate R&I
SPONSOR 05 Review Risk Assessed -Multi Centre	Please see SOP S-1003 UHL Appendix 4 to determine whether a risk assessment is required. If a Risk Assessment is required then please use this Workflow. If not please use NO RISK ASSESSMENT.		Corporate R&I
SPONSOR 06 Review Risk Assessed -Single Centre	If a Risk Assessment is NOT required then please use this Workflow. If one IS required please use the RISK ASSESSMENT workflow.		Corporate R&I
SPONSOR 07 Safety Reporting - Multi Centre	This Workflow must be added for each study where UHL is the Sponsor for a Single Centre Study		Corporate R&I
SPONSOR 08 Safety Reporting - Single Centre	This Workflow must be added for each study where UHL is the Sponsor for a Single Centre Study		Corporate R&I
SPONSOR 10 Study Training - Single Centre	Add this Workflow for all studies where UHL is the Sponsor - Single Centre		Corporate R&I

SPONSOR 11 DSUR	This workflow must be added to every study where a DSUR will be required in accordance with SOP S-1004 UHL		Corporate R&I
SPONSOR 12 Finance Approval	This workflow is to be used to show the Finance Approval for all Studies that UHL Sponsor.		Corporate R&I
SPONSOR 13 General Workflow	This workflow must be added to every study where UHL is the Sponsor.		Corporate R&I
SPONSOR 15 PIS / ICF Review	The workflow to be used when reviewing PIS / ICF for studies Sponsored by UHL		Corporate R&I
SPONSOR 16 Site Audits	This workflow must be added for each study that is Sponsored by UHL and where a Site Initiation is required as stated in SOP S-1011 UHL.		Corporate R&I
SPONSOR 17 Site Close Down	This workflow must be added for each study that is Sponsored by UHL and where a Site Initiation is required as stated in SOP S-1011 UHL.		Corporate R&I
SPONSOR 21 Annual Reports	To be completed for studies where a DSUR is due to be sent to regulatory authorities.		Corporate R&I

SPONSOR 22 Multi Centre Amendment	To be added every time an amendment requires R&I Approval/Acknowledgement. This includes substantial and non-substantial amendments, regardless of Categorisation. The Amendment Type/Number/Date must be included in the workflow comment.		Corporate R&I
SPONSOR 23 Urgent Safety Measures (Single Centre)	This workflow should be completed when an USM has been implemented for a Single Centre Study		Corporate R&I
SPONSOR 24 3rd Party Vendors	To be added where external / 3rd party vendors are to be contracted to deliver aspects of a research study where UHL is the Sponsor		Corporate R&I
SPONSOR 25 Contracts Process	To be added to studies were UHL is Sponsor and contracts are to be negotiated		Corporate R&I
SPONSOR 26 Substantial Amendment Review	To be added every time a Substantial amendment requires Sponsor authorisation. The Amendment Type/Number/Date must be included in the workflow comment.		Corporate R&I
SPONSOR 27 NON Substantial Amendment Review	To be added every time a Non Substantial amendment requires Sponsor authorisation. The Amendment Type/Number/Date must be included in the workflow comment.		Corporate R&I

SPONSOR 34 Site Pharmacy Close Down	This workflow must be added for each study that is Sponsored by UHL and where a Site Initiation is required as stated in SOP S-1011 UHL.		Corporate R&I
Study Staff Added	To verify that all staff have been added to EDGE appropriately That all training & certificates have been uploaded and relevant contracts obtained.	For Every Study	Any staff facilitating study set up - Speciality Team