1. Introduction

This Standard Operating Procedure (SOP) describes the process and utilisation of the UHL instance of EDGE. The EDGE system is set up with numerous 'instances' e.g. Organisational access (CRN-EM & University of Leicester). This SOP relates only to the UHL Instance.

1.1)
The EDGE system may also be known as the Local Portfolio Management System (LPMS) and will be used by the Clinical Research Network – East Midlands (CRN-EM) to capture data relating to Portfolio activity at UHL. It is also designed to feed directly into the Central Portfolio Management System (CPMS).

1.2)
It is important to recognise that the EDGE system is the only system utilised by UHL and Research & Innovation to manage detailed information about research activity within UHL whether or not the activity is adopted onto the NIHR Portfolio.

1.3)
This SOP is not designed to be an EDGE User manual, more an aide memoire and instruction document about how UHL utilises the system. A user manual which details all the functionality of the system can be found within the EDGE system along with individual working instructions stored in the General Documents section of the database.

2. Scope

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

3. EDGE Users

3.1) Administrator User

Administrator users will be staff employed only within the UHL R&I Office or with specific remit within a Support Department to assist with the utilisation of specific functionality. Administrator users have access to wider functionality of the EDGE System. Changes to the EDGE System must only be completed by an Administrator User.

(3.1.1)
In addition, an enhanced administrator will be the Business Intelligence Manager within the UHL R&I Office only.

3.2) Active EDGE User – with Log-In

EDGE Users require an EDGE Log-in to access individual study information. Active EDGE Users are given individual access on a study by study basis. Administrator Users are able to add new Active EDGE Users who do not have access. Once an EDGE User has activated their log-in and been added to a study, they may update their information to 'manage' some areas of the study record and, where appropriate, may also enable 'clinical' access to allow input of recruitment data.

3.3) Inactive EDGE User – Without Log-In

This EDGE status applies to individuals added to the 'staff' area within the SITE Level (RED) or Project Level (GREEN) of the EDGE record who do not require an EDGE Log-In but are named on the Delegation of Authority Log. Any individual involved with any study recorded on the EDGE database may receive Log-In details. The EDGE Administrator Users can add these at any time.

4. Recording Activity on the System

The intention is that all research related activity be recorded onto the EDGE system. Types of activity to be recorded include:

- Expressions of Interest
- Feasibility
- Capability
- Bid / Grant submissions
- Sponsor applications
- Research studies

4.1)

All information that relates to the activity will also be recorded. This includes, but is not limited to:

- Recruitment data
- All related documentation
- Details of staff involved
- Staff qualifications & training records
- Key dates
- Involvement of Support Services
- Information Governance Flow Mapping
- Contractual information
- Data Assets
- Lead CMG and supporting CMGs

4.1.1)

Once a record has been created for a particular activity, relevant personnel may be added to the record in order for them to assist with the completion of the relevant sections of the system. Completion of the EDGE record is encouraged by all, as it informs the latest position.

5. Use of Entities (Attributes) and Workflows

The EDGE system uses a series of Entities (Attributes) and Workflows to record specific information. UHL has developed a system whereby attributes and workflows are added to a specific record to give the answers to specific questions.

5.1)

Both Attributes and Workflows are designed with a specific line of questioning in mind. These Attributes and Workflows must be added to records as required.

5.1.1)

Information about which Attributes and Workflows must be added to records can be found in the EDGE System under 'General Documents'. The information about Attributes and Workflows to be added to every study is entitled:

- 'Additions for every study added to EDGE'.

5.1.2)
In addition to this two documents existentitled:

- Attributes – when to use them
- Workflows – when to use them

5.1.3)
These documents outline the Attributes and Workflows required by UHL and R&I. Most of the Attributes and Workflows should be added to the Project Level (GREEN) of the study record.

5.2) Use of Entities (Attributes) and Workflows by Specialty areas
In addition to the baseline information required by the Trust and R&I, there is often a requirement by individual study teams or departments to record information specific to those areas. In these cases, Entities or Workflows may be designed and used within the Project SITE Level (RED). These must be completed by the personnel within the specialty and it must be made clear whether or not full completion must be prior to confirmation of R&I Authorisation.

5.3) Use of Entities (Attributes) and Workflows by Support Departments
Support Departments are actively encouraged to utilise the functionality within the EDGE system to evidence the approval process for the specific area. The process will be developed with personnel from each area.

5.3.1)
At the time of authoring this SOP the Support Departments currently using the system to process approvals are:

- Imaging
- Cardiac Investigations
- Medical Devices
- Pharmacy
- Laboratories
- Nuclear Medicine

6. Completion of Entities (Attributes) and Workflows
Completion of most Entities and Workflows must be done before R&I Authorisation is confirmed. It is clear within Entities and Workflows when they are not required to be completed prior to Authorisation.

6.1)
All users, but specifically specialty personnel and R&I study support officers, are encouraged to complete EDGE Attributes and Workflows as a study progresses through the Assess, Arrange & Confirm Process as detailed in SOPs C-2006 UHL, C-2006a UHL, C-2007 UHL, & C-2008 UHL.

6.2)
A study will not be authorised by UHL R&I unless all required Entities and Workflows are satisfactorily completed.

7. Staff Listed within EDGE Levels

Staff with access to the EDGE levels will have a variety of roles in relation to the specific study record. Some will require access to the Project (Green) or Site (Red) Levels, while others will additionally require access to the Patient Level.

7.1)

The Delegation of Authority Log list of personnel held within the site file will not match those listed on the Project or Site Levels of the EDGE record. There is no requirement for all personnel listed within the EDGE record to be listed on the Delegation of Authority Log. However, there is a requirement for all personnel listed on the DoA to be listed within the Site (Red) Level of the study record. In addition, it is expected that all personnel listed on DoAs will have a completed training record on EDGE.

8. Documents

8.1) Project Level (Green) Documents

A template of folders exists within the EDGE system. Documents to be stored on the Project Level must be those relating to those studies that UHL Sponsor only.

8.1.1)

Where a document exists that cannot be filed within the existing folder structure, the functionality exists to enable additions of individual files or folders.

8.2) Site Level (Red) Documents

A template of folders exists within the EDGE system. Documents to be stored on the Project Site Level must be those relating to those studies that UHL Host only.

8.2.1)

Where a document exists that cannot be filed within the existing folder structure, the functionality exists to enable additions of individual files or folders.

9. Data Verification

It is essential to ensure that all data added to EDGE is accurate. In order to assure accuracy Corporate R&I will undertake to randomly check data on the following Attributes:

- Mandatory Category 1
- Laboratory Involvement (CTIMP)
- Laboratory Involvement (Non-CTIMP)
- Data Flows / GDPR
- Medical Devices & Equipment
- Pharmacy Involvement

9.1)

A random sample of approximately 10 per cent of activity will be verified on a monthly basis. Data Verification Workflow (Green Level) will be added to each study as verification take place. Inaccuracies or missing data will be noted in the Data Verification Report (Appendix 1). The report will be reviewed on a monthly basis by the Head of Research Operations and R&I Manager and relevant action plans devised.

9.2)

Action will be taken to address the issues identified with the appropriate staff groups. This may be Study Support Officers, Clinical Teams or Administrators.

10. Responsibilities

	Responsibility	Undertaken by	Activity
1	R&I Office	R&I Personnel	Add projects to EDGE, adding relevant attributes & workflows
2	EDGE Administrators	EDGE Administrators	Add users, access, attributes & workflows to projects as required.
3	EDGE Users	EDGE Users	Assist with ensuring all data is accurate on all records

11. Who Guideline Applies To

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

12. Education and Training

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

13. Education and Training

None

14. 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

15. Supporting Documents and Key References

SOP C-2021 Appendix 1

SOP C-2006

SOP C-2006a

SOP C-2007

SOP C-2008

16. Key Words

Research, Innovation, EDGE, REC, MHRA, HRA, CPMS, LPMS

17. 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**	

18.

This line signifies the end of the document

18.1)

This table is used to track the development and approval and dissemination of the document and any changes made on revised / reviewed versions

18.2)

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT		
Author / Lead Officer:	Carolyn Maloney	**Job Title:** Head of Research Operations
Reviewed by:	UHL R&I Management Meeting	
Approved by:	Professor Nigel Brunskill	**Date Approved: PGC 19.3.21**

Data Verification Exercise Report

EDGE ID:	Date Verification Exercise:

Attribute Name	Incorrect / Missing data	Action plan to address	Actions completed
1. MANDATORY CATEGORY 1			
PID Clinical Trial			
Portfolio Studies			
IRAS Reference No.			
Study Category			
Education			
Multi Centre			
Is UHL Lead Centre?			
Lead Centre Name if not UHL			
Sites Identified			
Type of Research			
Regulatory Approvals			
Methodology			
Primary Clinical Management Areas			
Secondary Clinical Management Area			
Type of Sponsor			
Location of Sponsor			
Support Department			
Type of Funding			
Definition of End of Trial			
Patient Population			
Primary Research Question			
Secondary Research Question			
Outcome Measure			

Device Study			
NIGB Approval (CAG Approval)			
Antimicrobial Agent or Process used			
Monitoring Arranged (Monitoring Arranged)			
Name of CRO/CRA Company used			
CRO/CRA (CRO/CRA used)			
PPI (Patient Public Involved in Study)			
Translation Services (Using Translation Service)			
Accessible to BME			
Lack of Capacity (Lack of Capacity to Consent)			
PLR Used (A PLR has been identified)			
Insurance (Type of Insurance)			
ARSAC Certificate Required			
Information Governance			
NIPAG approval required			
Ionising Radiation ticked in IRAS			
Have you involved UHL Libraries			
Study uses APPS/AI/Data Driven Technologies			
2. LABORATORY INVOLVEMENT (CTIMPS ONLY)			
Added Samples / Tissue Workflow			
Sample Collected from			
Tissue Consent obtained for			
Samples Storage Status			
Type of Samples to be stored			

New Sample			
Surplus Sample			
Archived Sample			
Cells for Human Application			
Analysis of DNA			
Central Lab Used			
Name & Address of Central Lab if used			
Which samples will go to Central Labs			
Accredited Lab Required			
Name of accreditation scheme			
Licensed Tissue Bank			
Licensed Tissue Bank (Details)			
Samples imported from outside UK			
Originating Country of Samples			
Type of Samples collected			
Sample Processing			
Name of UHL holder of samples during study			
Location of ALL samples during study activity			
Type of Sample tracking adopted			
Name of Sample tracking adopted			
Where will samples be processed for shipping			
Final Destination of Samples outside of UHL			
Final Destination of Samples within UHL			
Will samples be exported from UHL to outside UK			

Type of Test / Analysis to be carried out			
Which analysis provided through UHL Lab Services			
Activity at UHL Labs - tick all that apply			
Tissue Disposal Arrangement			
Archived UHL Labs			
Archived External to UHL			
Sample Freezers / Fridges on temp control system			
Name of Temp Control system used (Int. Only)			
SOP for reporting Temp deviations (Int. Only)			
Are Freezers / Fridges linked to Emergency backup			
Is this a dose escalation study			
Analysis carried out by Sub-Contractor to UHL			
List Sub-Contracting Tests & Organisation/s			
3. LABORATORY INVOLVEMENT (NON-CTIMP)			
Added Samples / Tissue Workflow			
Sample Collected from			
Tissue Consent obtained for			
Samples Storage Status			
New Sample			
Surplus Sample			
Archived Sample			

Cells for Human Application			
Analysis of DNA			
Type of Samples collected			
Type of Samples to be stored			
Sample Processing			
Samples imported from outside UK			
Originating Country of Samples			
Location of ALL samples during study activity			
Will samples be exported from UHL to outside UK			
Name of UHL holder of samples during study			
Type of analysis conducted - list all detailed			
Which analysis provided through UHL Lab Services			
Central Lab Used			
Name & Address of Central Lab if used			
Licensed Tissue Bank Used			
Licensed Tissue Bank (Details)			
Accredited Lab Required			
Name of accreditation scheme			
Name of Sample tracking adopted			
Type of Sample tracking adopted			
Tissue Disposal Arrangement			
Archived External to UHL			
Archived UHL Labs			
Final Destination of Samples outside of			

UHL			
Final Destination of Samples within UHL			
Sample Freezers / Fridges on temp control system			
Name of Temp Control system used (Int. Only)			
SOP for reporting Temp deviations (Int. Only)			
Are Freezers / Fridges linked to Emergency backup			
4. DATA FLOWS / GDPR			
Legal Basis for Collection of Data			
Is the Data Special Category			
What Data will the Data Collection Tool(s) Hold			
What is the Data			
Is it Bulk Data			
Name of Data Capture Tool(s)			
Type of Data Collection Tool(s)			
Description of Data Capture Tool(s)			
Is data already collected for clinical purposes			
Is relevant access authorised			
Data Flow Mapping			
Data Leaving UHL			
Ext. Trans - Docs sent to Privacy			
Ext. Transfer - DPIA required			
Purpose of Transfer			
Does data leave the originating			

department			
Specific Address of Originating Data			
Specific Address of Destination for Data			
Additional details of all data flows			
Legal Cover for Flow of Data			
How is Data Sent			
Is information provided via other teams			
Are you collecting Children's PCD			
Staff roles defined for Data Collection			
Staff roles defined for CRF Completion			
How are access controls managed			
Staff added to Delegation Log			
Are staff trained on the system and how			
Electronic CRF - access arranged			
Frequency of collection agreed			
Mobile equipment used			
Point of contact for data queries confirmed			
Is 3rd party access allowed			
Where Sent to 3rd parties Only			
Data leaving UK - Destination in EU			
Registration number for 3rd where appropriate			
Does a Confidentiality Agreement exist			
Is there a Data Sharing Agreement in place			
Are there defined access controls			
Does Data Collection Tool(s) Remote Access exist			

Other HCP Social Care access - name protocol			
Registration / Deregistration process			
Password Strength - Define			
Who will the data be shared with			
In what Media is Data Set Stored			
Data stored electronically - where?			
Information Asset Owner			
IAO Administrator			
Name of Data Controller/s & Organisation			
Name of Data Processor / s & Organisation			
Business continuity plans in place			
Data capture tools recorded on UHL Asset Register			
Could the data re-identify with the right access			
How long will the data set be stored			
How will information be disposed of			
Date data to be destroyed			
CAG Studies ONLY - Opt Outs considered			
IG USE ONLY - Audited			
IG Additional comments			
5. MEDICAL DEVICES / EQUIPMENT			
What is / are the status of the equipment/device			
What is the purpose of the study			

MHRA Approval			
Type of equipment used in study			
Is equipment required specifically for the study			
Is equipment provided by the sponsor			
Equipment already delivered			
Estimated date of delivery - if not already at UHL			
Indemnity Arrangements			
Space for equipment			
Equipment used at home			
Loss or Damage cover			
Equipment Training			
Calibration / Maintenance records			
Named person/dept responsible for calibration			
Equipment based at other site			
What happens to equipment at end of study			
6. PHARMACY INVOLVEMENT			
Primary IMP (Name of IMP used in study)			
Secondary IMP			
Third IMP			
Fourth IMP			
Fifth IMP			
IMP Status (Is the IMP licensed or not?)			
Type of IMP (Type of IMP in use)			
IMP Risk Rating (Risk Based			

assessment criterion)			
IMP off Label (Use of IMP off label)			
Bioequivalence or Bioavailability Study			