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) amd 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 exist entitled:

- 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)

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Author / Lead Officer:	Carolyn Maloney	**Job Title:** Head of Research Operations
Reviewed by:	UHL R&I Governance Meeting	
Approved by:	Professor Nigel Brunskill	**Date Approved:** 09/07/2021.

REVIEW RECORD			
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