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 Comprehensive 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 the UHL Trust and Research & Innovation to manage detailed information about research activity within Sponsored by UHL.

1.3)
This SOP is not designed to be an EDGE User manual, more an aide memoire and instruction document about how UHL utilise the system. A user manual which details all the functionality of the system can be found within EDGE 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 Sponsored by the University Hospitals of Leicester NHS Trust (UHL).

3. Project Ownership
The owner of an EDGE record has control of the main study page. It is expected that all research Sponsored by UHL is 'owned' by UHL. Where UHL are not the owners, a request will be made to transfer the ownership.

4. Sponsor Entities (Attributes) / Workflows

A list of Sponsor specific Entities and Workflows have been written to manage the entire Sponsor process and are designed to follow a study from initial sponsor review through the lifecycle to confirmation of publication. The aim of workflows is to confirm that a process has taken place. The aim of entities is to capture answers to specific questions.

4.1)
There are many aspects of Sponsor responsibilities that duplicate those of a Host Organisation. It is for this reason that both the required Sponsor specific Entities / Workflows and others required for working a study up as a Host Organisation should be added and form part of the Sponsor review process.

4.2)
The aim is to record information once. It is for this reason that many reports will include Sponsor specific details and those of other Entities and Workflows. This reduces duplication of effort and provides a smooth and more coherent sponsor process.

5. EDGE Users

5.1)
Administrator User
Administrator users will be staff employed only within the UHL R&I Office or with specific remit within a Clinical management Group (CMG) Support Department to assist with 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.
In addition, an enhanced administrator will be the Information Manager within the UHL R&I Office only.

5.2)
Active EDGE User – with Log-In
EDGE Users require an EDGE Log-in in order to be able 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.

5.3)
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.

6. 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
- Safety Reporting/deviations

6.1)
All information that relate to the activity will also be recorded. To include but 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

6.2)
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.

7. Use of Entities (Attributes) and Workflows

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

7.2) In addition to this, two documents exist entitled:

- Attributes — when to use them
- Workflows — when to use them.

7.3)
These documents outline the Attributes and Workflows required by the UHL Trust and R&I. Most of the Attributes and Workflows should be added to the Project Level (GREEN) of the study record.

8. 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.

8.1)
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 & C-2008 UHL.

8.2)
A study will not be authorised by UHL R&I unless all required Entities and Workflows are satisfactorily completed.

9. 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.

9.1)
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.

10. Documents

10.1)
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.

10.1.1)
Where a document exists that cannot be filed within the existing folder structure, the functionality exists to enable additions of individual files or folders.

10.2)
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.

10.2.1)
Where a document exists that cannot be filed within the existing folder structure, the functionality exists to enable additions of individual files or folders.

11. Managing Multi-Centre Research

Where UHL are the lead centre and sponsor for multi-centre research, Workflows have been developed to assist with the management of all aspects of multiple site oversight. Where Sites are existing EDGE users the UHL Sponsor staff are added to the site instance and relevant workflows added. Where the Site are not EDGE users, an agreement has been made with EDGE for those sites to be added to the UHL Instance. Workflows and UHL Sponsor personnel are the only additions made to these sites. Recruitment, key dates and status are not managed as this would only serve to compromise national reporting.

12. 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
4	Chief Investigator/Principal Investigator	Chief Investigator/Principal Investigator	Ensure the posting of clinical trial publications to EudraCT and any relevant research databases.

13. Who Guidelines Applies To

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

14. Guideline Standards and Procedures

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

15. Education and Training

None

16. 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

17. Supporting Documents and Key References

SOP C-2006
SOP C-2006a
SOP C-2007
SOP C-2008

18. Key Words

Research, Innovation, EDGE, REC, LPMS, CRN, CPMS

19. 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**	

20.

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20.1)

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

20.2)

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