

EDGE Database Management & Terms of Use

**IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT
THE CORRECT VERSION IS BEING USED**

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: www.research.yorkhospitals.nhs.uk/sops-and-guidance/ and/or Q-Pulse

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This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	20 th November 2009	
2.0	1 st August 2010	Clarification of aspects of clock management
3.0	28 th October 2013	Change of SOP Controller. Removal of references to the North and East Yorkshire R&D Alliance. Added Appendix B to explain 'Status' definitions.
4.0	10 th November 2014	Add actions needed with regard to 1 st patient recruitment monitoring
5.0	29 th June 2016	SOP reviewed due to change of database used.
6.0	17 th August 2017	
7.0	21 st February 2019	Change to link for R&D website. Removal of the 'Private' function reference
8.0	8 th April 2019	Change of wording of Public to Published
9.0	22 nd July 2019	More details added on Access & Training, Terms of Use, Contingencies and Maintenance. Appendix 1: Management of user access levels to the EDGE system added.

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1 Introduction, Background and Purpose

The York and Scarborough Teaching Hospital NHS Foundation Trust R&D Unit uses an external online database called 'EDGE'. The EDGE Clinical Research Management System is available to support research governance activities and to monitor and report on research participants' recruitment within the Trust.

The database is an essential tool that allows the R&D Unit to maintain a record of the research activity being carried out within the Trust, therefore fulfilling a core requirement of the Research Governance Framework for Health and Social Care 2017.

The purpose of this SOP is to clarify the use of the database to all local EDGE administrators and users.

2 Who Should Use This SOP

All R&D Unit research delivery and support staff within the York and Scarborough Teaching Hospitals NHS Foundation Trust with an access account to the EDGE system.

3 When this SOP Should be Used

This SOP should be followed when staff members are accessing the EDGE system to either: view, enter, or amend data on EDGE.

4 Procedure(s)

4.1 Database Administrators and Users

EDGE system is a web-based system accessible using a username and password from any device with an internet connection. Appropriate access rights have to be granted by designated Local Administrators to enable the individual to use the system. It is the choice of the R&D Unit as to how many local Administrators there are, usually a minimum of 2.

The local Database Administrators have access to certain functions of the database that other local users do not. The level of access for each user that is initially set can be amended by the Data Administrators at any time upon request. Appendix 1 details the R&D Unit management of user access levels to the EDGE system.

4.2 Using the Database

Purpose of use:

The priority use of the database is to maintain a record of all research activity within the Trust including recruitment of research participants and accrual reports.

The Secondary uses for the database are:

1. Keeping a record of study documents.
2. Keeping a record of invoices.
3. Running reports.
4. Using EDGE *General Documents* as a central repository for research staff training documents (research CVs & GCP Certificates).
5. Using *Workflows* for project governance purposes.
6. Using *Entities & Attributes* at Project & Project Site level for tracking, communication and reporting purposes.

Terms of use:

In addition to the Trust policies relating to the processing of patient data, research staff members are also required to adhere to the following requirements listed below:

1. Only the minimum required patient identifiable data should be entered into EDGE. I.e. Study ID, NHS Number, Name, DOB, gender. (Address, telephone number, GP details are NOT required). The EDGE *Patient Data Collection Plan* assigned to individual research projects determines the patient identifiable details that are mandatory to enter under the *Patients* tab. These details can only be entered by *Users* with the EDGE *Clinical Access* rights. The R&D Research Facilitators assign the appropriate *Patient Data Collection Plan* to each project at the study set up stage. The required patient identifiable details depend on the study type and the requirements and logistics of patient recruitment.
2. Staff with access to patient identifiable data (*Clinical Access*) within EDGE must only access the data which they have a legitimate reason to do so for the purposes of supporting clinical research activity.
3. Patient identifiable data must not be accessed outside of Trust premises. Staff accessing other functions within the EDGE Clinical Research Management System should do so only via Trust approved, encrypted devices and ensure that they 'lock' or log-out of terminals/devices immediately when not in use.
4. Confidentiality markings must also be used on all reports/documents printed from the system which contain staff or Trust sensitive information.
5. Individuals must not share their username or password with other individuals or permit other users to access EDGE via their account. Any unauthorised use must be reported to the Local System Administrator/s to enable a password reset, and system audit to identify any potential security breaches. All activity on the system is auditable and periodic and ad hoc

audits will be conducted by the EDGE Administrators who are able to establish who has logged into the system and what information has been edited.

6. Each user is responsible for ensuring they have received adequate training on the system and for ensuring they comply with this document; however it is also the Line Manager's responsibility to ensure that their staff are compliant and adequately trained.

EDGE Access & Training:

New Starters are issued with access details and provided with an overview of the system as part of their local induction programme by the local EDGE Administrator/s. For any members of staff leaving their research post the EDGE user log on details are deleted by the EDGE Administrator/s and account deactivated. Line Managers are responsible for informing local Administrators when staff require access granting or removing from the system.

Complete audit trail of all users, including deactivated accounts, remain available on the EDGE system. Periodic audit checks of all local EDGE Users (*user details, account status and access type, including project access level for active users*) will be carried out by the EDGE Administrators to ensure that the appropriate access level and confidentiality of study data are maintained (as a minimum annual audit check should be carried out and documented).

4.3 Adding a study on EDGE

New studies are added to EDGE by the Research Delivery Facilitators or R&D Administrators/ or Trial Managers with the *Admin User* access as part of the R&D research governance procedures.

Before a study can be added to the database, a search has to be done to see if it is already on the database.

1. Log onto EDGE using the sign on allocated by an Administrator then click on the Project tab at the top of the page.
2. Complete one of the blank fields, click on Global Projects (under the heading Project Type). If a project is already registered, it will appear in the Search Results box, click on study title.

From there select the Organisations tab – this will list all organisations participating into that study. Click the Request Involvement button on the top right. This could take a few of days to be verified and will show in the Notification area on the Home Screen. Once approval has been granted, by clicking on the Staff tab you should be able to assign yourself as a member of staff to the study and continue with set up.

Each study requires a unique R&D number. This is the IRAS number followed by a Y for York Teaching Hospital or S for Scarborough Hospital (e.g. 123456Y).

3. Select Site tab on left hand side, click Add Project Site and complete details and save.
4. From the tabs along the top, select Staff, Add Teams/s or User. R&D need to be added to every study and the Manager box ticked. Other teams can be added by using the same method. These should be given clinical access only unless requested.
5. Select File tab from the left hand side of the screen, Click Templates, Add folders from Templates, Add R&D File. This now shows all the categories that are required for Capacity & Capability.

See 4.6 for adding files to the folders.

4.4 Amending Details

Only Users with *Management Rights* can amend project details.

Search for the study under *Assigned Projects*, the study should appear in the Search results. Click on the site required (highlighted in blue on the right hand side). This will take you to the 'RED' area (local project).

Click the Edit button and make changes then Save.

4.5 Confirming Capacity & Capability

Once Capacity & Capability has been granted EDGE database amendments must be carried out. This can be done by following the instruction as in 4.4 and completing the details from the dropdown options.

4.6 Uploading Folders & Files

Only Users with *Management Rights* can upload folders & files under the relevant assigned projects.

This is done in the '*Local*' view by selecting the file tab

1. Click on folder required (eg Protocol)
2. Click Add file from the top right hand side
3. Select file & find the document you wish to upload
4. Tick Published & complete Version number if relevant
5. Upload
6. Once all documents have been uploaded into that folder, click back on the Files tab on the left hand side. This will take you back to the list of Folders.
7. Additional folders can also be added to your list by clicking Add Folder from the top right hand side. Name folder & tick Published.

NB: If superseding a document then it will be necessary to 'un-tick' Published from the old version. By doing this only the current version of the document will be visible to everyone.

4.7 Contingencies – EDGE Business Continuity Plan

In the event of the EDGE Clinical Research Management system being unavailable staff should consult the IT Service Desk for guidance in the first instance and enquire regarding local issues which may be affecting access.

If unresolved, the local EDGE Administrators should be informed in the first instance. They will liaise with the EDGE central team as appropriate.

If the system fails – electronic copies of study documents as saved for research governance purposes are available on the R&D shared drive as a backup option – please consult the local EDGE Administrators regarding document location & access. All essential study documents are also maintained by the relevant Research Teams and Support Departments and kept up to date within the study Investigator Site Files.

4.8 Maintenance of up to date study records on EDGE

The EDGE Clinical Research Management System is managed by the York Trust Research & Development Unit staff with user access and document management procedure as outlined in section 4.

Site level details for York Trust projects are regularly checked and confirmed at the local Research Portfolio Meetings between the R&D Research Facilitators and Research Teams. Any identified changes in study set up, recruitment status or staff changes are subsequently update on the system.

All activity on the system is auditable and periodic and ad hoc audits will be conducted by the local EDGE Administrators.

5. Appendices

5.1 Appendix 1

The following User Access Levels are available for the EDGE system:

- Access levels to the EDGE system :
 1. *Admin*
 2. *User*
 3. *Inactive User*

- Access levels when an EDGE User is assigned to a project (project settings):
 1. *View Rights*
 2. *Manage Rights*
 3. *Clinical Rights*

EDGE User Access to the system:

1. Admin

Full edit rights to all aspects of EDGE: assign project access level, request involvement to project, access to Management/ Library/ Reports.

Admin access is assigned & set up for R&D Unit staff by the local EDGE Administrators based on individual job roles & responsibilities. Further project specific settings (*view rights, manage rights & clinical rights*) are assigned on study by study basis by the Research Delivery Facilitators at the study set up stage.

R&D Unit EDGE Admin Users:

- Head of R&D (purpose: to access Management/ Library/ Reports)
- Research Delivery Facilitators (purpose: to assign project access level, request involvement in projects)
- R&D Administrator/EDGE Administrator (purpose: local EDGE Admin 1)
- R&D Administrative Co-ordinator (purpose: local EDGE Admin 2)
- Research QA Manager (purpose: local EDGE Admin 3)
- Research Advisor (purpose: to access Management/ Library/ Reports & to assign project access level, request involvement in projects for Trust Sponsored studies)
- R&D Administrator (purpose: to access Management/ Library/ Reports)
- R&D Trial Managers (purpose: to access Management/ Library/ Reports to assign project access level, request involvement in projects for Trust Sponsored studies)
- R&D Trial Administrator (purpose: to access Management/ Library/ Reports & to assign project access level, request involvement in projects for Trust Sponsored studies)

2. User

Can only assign user access to a project/project site they have manage rights for/ not able to edit any aspects of EDGE as a system.

Users are assigned & set up for R&D Unit staff by the EDGE Administrator based on the individual job roles & responsibilities. Further project specific settings (*view, manage rights & clinical rights*) are assigned on study by study basis by the Research Delivery Facilitators at the study set up stage.

R&D Unit and research delivery EDGE Users (including support departments):

- Senior Research Nurses

Research delivery staff and support department's staff:

- Research Nurses
- Clinical Trials Assistants
- Research Practitioner/s
- Data Manager/Research Administrator/s
- Pharmacy Clinical Trials Team
- Laboratory Research Team

3. Inactive user

No EDGE access. Although an account can be created without activating it e.g. for a study PI/CI.

EDGE User access specific to a project (Project Settings):

1. View Rights

READ ONLY access (project site information, excluding access to the patient specific details.)

View rights are assigned to EDGE Users by Research Delivery Facilitators as study set up stage.

View rights are set up for support departments' staff with the purpose of enabling them to view project details without edit access.

2. Manage Rights

A User assigned as a Project site Manager will automatically be given read /write access to this project site. This user will be able to edit any of the data their organisation can access. Having manager access will not allow the user to see the specific patient information. Only Clinical Permission will allow this.

Manage Rights are assigned to EDGE Users by Research Delivery Facilitators at study set up stage on study by study basis. A User must have Manage rights assigned to a project to be able to upload documents onto EDGE.

Manage Rights are set up for:

- All Admin Users are assigned Manage Rights to all projects as a default at study set up for the purpose of enabling them read/write access to all projects (Trust sponsored & hosted) so they can access & upload study documents related to EOI, set up, amendments, QA, finance, study close out & archiving.
- Users that require read/write access to a project, for example Research Nurses leading on certain projects are assigned Manage Rights to be able to edit information/upload documents for the assigned projects.

3. Clinical Rights

All staff members at site level who will be actively recruiting patients to a project will need to have clinical access. This includes administrative staff who are entering recruitment details on someone else's behalf.

Users can have both Management and Clinical access, or alternatively a user can have neither & read only access

Clinical Rights are assigned to EDGE Users by Research Delivery Facilitators at study set up stage on study by study basis.

- Clinical Rights are set up for all Research Nurses and Clinical Trials Assistants/ Administrative Support Staff who are entering recruitment details for research projects.