

EDGE Database Management

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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.northyorksresearch.nhs.uk/sops.html and/or Q-Pulse

SOP Reference:	R&D/S15
Version Number:	6.0
Author:	Angela Jackson
Implementation date of current version:	17 th August 2017

Approved by:	Name/Position:	Lydia Harris, Head of R&D
	Signature:	Signed copy held by R&D Unit
	Date:	17 th July 2017
	Name/Position:	Sarah Sheath, SOP Controller
	Signature:	Signed copy held by R&D Unit
	Date:	17 th July 2017

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	

Contents

	<u>Page No</u>
1 Introduction, Background and Purpose	1
2 Who Should Use This SOP	1
3 When this SOP Should be Used	1
4 Procedure(s)	1
4.1 Database Administrator and Users	1
4.2 Using the Database	1
4.3 Adding a study on EDGE	1
4.4 Amending Details	2
4.5 Confirming Capacity & Capability	2
4.6 Uploading Folders & Files	2

1 Introduction, Background and Purpose

The York Foundation Trust R&D Unit uses an external online database called EDGE.

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.

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

2 Who Should Use This SOP

All staff working in the York Foundation Trust R&D Unit with write-access to EDGE.

3 When this SOP Should be Used

This SOP should be followed when staff are entering, deleting or managing data on EDGE.

4 Procedure(s)

4.1 Database Administrator and Users

The Database Administrator has access to certain functions of the database that other local users do not. The level of access for each user is initially set can be amended by the Data Administrator at any time.

It is the choice of the R&D Unit as to how many Administrators there are, usually a minimum of 2.

4.2 Using the Database

The priority use of the database is to maintain a record of all research activity within the Trust including accruals.

The Secondary uses for the database are

1. Keeping a record of study documents
2. Keeping a record of invoices
3. Running reports

4.3 Adding a study on EDGE

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

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

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 Public & Published & complete Version number is 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 Public.

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