

SOP number	59.013	Version	1.0
Title	Administration of Research Projects		

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SOP category	West of Scotland Safe Haven																							
Staff category																								
<table><tr><th>Staff Category</th><th>R</th><th>A</th><th>C</th><th>I</th></tr><tr><td>West of Scotland Safe Haven Manager</td><td></td><td>X</td><td></td><td></td></tr><tr><td>Project Management</td><td>X</td><td></td><td></td><td></td></tr><tr><td>Data Processing Staff</td><td>X</td><td></td><td></td><td></td></tr></table>					Staff Category	R	A	C	I	West of Scotland Safe Haven Manager		X			Project Management	X				Data Processing Staff	X			
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1. Scope

This procedure applies to the Safe Haven within NHS Greater Glasgow and Clyde.

2. Purpose

The purpose of this SOP is to describe the procedures relating to administration and management of research projects within the Safe Haven.

3. Procedures

In general, the following guidelines should be adhered to:

3.1. Assigning project folders

On receipt of a study/project application a project folder will be created in the 'Applications' folder within the Safe Haven shared drive. The project folder will use the following naming convention: E.g. GSH/YY/AA/NNN_Project_Short_Name, in line with SOP 59.007.

Project_Short_Name – will be decided by the project manager based on either the project acronym or, in the absence of one, the project title.

This naming convention should be used for all project folders, regardless of the project.

3.2. Naming Project Documents

All documents will be named by attaching the project number to the beginning of the file name with a subsequent underscore before the file title. The documents will be placed and managed within the appropriate, named folder for each project.

3.3. Applying Project Phases

Projects (whether full extracts or feasibilities/aggregates) will move through seven different phases during their life cycle. These phases are:

- Active – Project is approved and being 'actively' worked on by the Safe Haven
- Inactive – Project is suspended
- Proposed – Project is not yet approved
- Follow-up – Project is approved and data extract is complete
- Withdrawn – Project was withdrawn after being approved
- Complete – Project has been fully realised and final outputs generated by/for researcher

3.4. Administration of Project Folders

All project folders will be named according to the above naming convention and will be structured according to Figure 1.

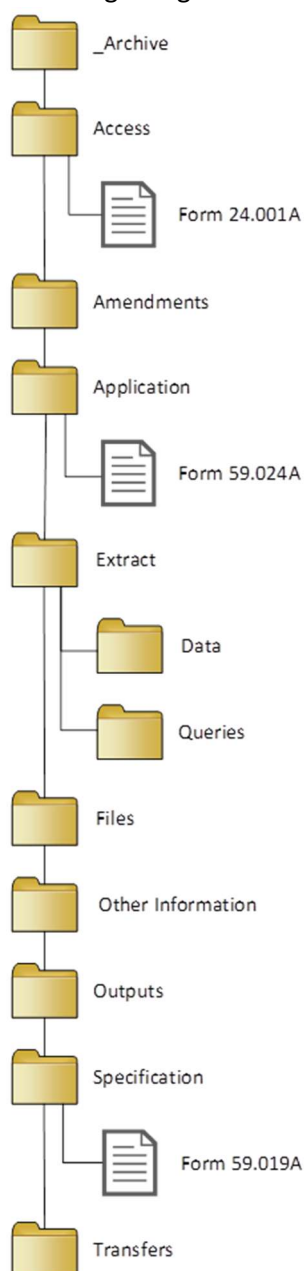


Figure 1 – Folder Structure

All project folders after creation of project in the database (GUI 59.013A), regardless of project type, will initially be held in the 'Applications to Safe Haven; folder on the shared drive. Once approved, the project folder will be moved in to the 'Safe Haven Projects' folder on the shared drive. On completion of the data extract (or aggregate) and once satisfied that all documentation is present and the project is either in 'complete' or 'follow-up' status, and quality management procedures have been applied, the Project Manager will move the project into the folder '1 Projects Complete Withdrawn and In Follow Up' within the 'Safe Haven Projects' folder in the Safe Haven shared drive.

3.5. Project Maintenance

Projects should be maintained within the Safe Haven Projects Register FORM 59.013A and according to Work Instructions GUI 59.013B, Form 59.013B, GUI 59.013C and GUI 59.013D.

4. Referenced documents

- SOP 59.007 - Assigning Study Numbers and Subject IDs
- FORM 59.013A - West of Scotland Safe Haven - Project Register
- FORM 59.013B - West of Scotland Safe Haven Notification of Amendment
- FORM 59.013C - West of Scotland Safe Haven Application Acknowledgement
- FORM 59.013D - Project Application Validation Checklist
- GUI 59.013A - Creation of a new (Extract) project
- GUI 59.013B - Creation of a Project Amendment
- GUI 59.013C - Adding to and Maintaining the Project Waiting List
- GUI 59.013D - Maintaining a Project

5. Related documents

- Data Management Plan

6. Document history

Version	Date	Description
1.0		Migration to Glasgow Clinical Trials Unit QMS

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