

SOP number	59.009	Version	1.0
Title	Administration of Research Projects		

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SOP category	West of Scotland Safe Haven			
Staff category				
Staff Category	R	A	C	I
West of Scotland Safe Haven Manager		X		
Data Management	X			
Data Processing Staff	X			
Database Development Staff	X			
Chief Investigator	X			
Principal Investigator			X	

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 the creation of project data specifications, which will form the basis of an agreement with the project research team and provide the template from which an analyst will work to create the project extract.

3. Procedures

In general, the following guidelines should be adhered to:

3.1. Create a Researcher Project Specification

A project specification will be prepared using an appropriate template, Form 59.009A - Researcher Project_specifications_Template. Guidelines for completing the specifications can be found within the template in the 'Instructions' tab.

The template will specify how the cohort will be built and extract produced using the criteria supplied by the PI or CI/research team.

To elicit the requirements a meeting should be held with the Safe Haven team (including a Safe Haven analyst) and the researcher.

3.2. Create a Safe Haven Project Specification

All project data specifications will be prepared for the Safe Haven analytical staff using the appropriate template, Form 59.006A - Project Specifications Template (General). Guidelines for completing the specifications can be found within the template 'Instructions' tab.

A risk assessment will be performed by the Safe Haven team which will define the level of checking required at both the cohort definition and the data extracts stages. This will be documented in the project specification.

3.3. Approval of a Safe Haven Project Specification

Once the specification is at an appropriate stage the Chief Investigator or Principal Investigator and the Safe Haven analyst will be required to approve the specification.

4. Referenced documents

- Form 59.006A - Project Specifications Template
- Form 59.009A - Researcher Project Specifications Template

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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