SOP number	**57.010**	Version	**4.0**
Title	**Study Planning, Set-up and Start-up**		

Prepared by Signature	Helen Hart Date
Approved by Signature	Lynn Prentice Date
Released by Signature	Julie Brittenden Date

SOP category	57 NHS GG&C Clinical Research Facility – Administration				
Staff category	**Staff Category**	**R**	**A**	**C**	**I**
	Nursing	X			
	Administration	X			
	Principal Investigator	X			
	Clinical Research Fellow	X			
	Information Manager	X			
	GCRF Manager		X		
	R&I Finance				X
	Site Clinical Trials Pharmacy				X
	Clinical Research Imaging Facility (CRIF)				X
	GCRF Associate Director				X
	Senior R&I Manager				X

1. Scope

This procedure applies to all staff working within Glasgow Clinical Research Facility (GCRF).

2. Purpose

The purpose of this SOP is to describe the processes before a research study can start recruiting. There are three stages:

- Planning
- Set-up
- Start-up

3. Procedures

3.1. Planning/feasibility

An assessment of the feasibility of conducting a study must be completed by the Principal Investigator (PI), Specialty Research Nurse or R&I Coordinator. To use the facility the PI must contact GCRF Management Team in the first instance to discuss potential study, passing on as much information as available. Feasibility should include resource availability, potential recruitment target, planned

recruitment strategy and clinical service impact on support departments (labs, pharmacy and imaging).

3.2. Site Selection Visit (SSV)

A Confidentiality Disclosure Agreement (CDA) may be signed between Sponsor and R&I before any document is released by the Sponsor.
An SSV may be arranged externally by the study Sponsor or Contracted Research Organisation (CRO) and will be coordinated by specialty Research Nurse. Relevant departmental support staff should also be included in the SSV (as appropriate pharmacy, labs and imaging).
During the SSV the capability and capacity of the CRF is assessed, the Sponsor feasibility may be conducted during the visit. GCRF Site Capability document GUI 57.010C, can assist with SSV.

3.3. To apply for GCRF support including room use

Once selected as a site Form 57.010A Study Support, alongside the clinical risk assessment Form 17.048A, should be completed by the PI and Research Nurse, and submitted to GCRF Planning Group, details on how to submit are on the forms. The GCRF Information Team will follow GUI 57.016B to create/request the study record on the web-based research information system, EDGE.

3.4. Planning Group Meeting

The GCRF Planning Group meet frequently to discuss potential studies. A report is raised from EDGE detailing studies at Feasibility, Concept and In Set-up. Each study is assessed to confirm it can be delivered in accordance with protocol and contract, and what level of support is required. The following will be considered during GCRF assessment:

- Number of conflicting studies using the same participant group
- Availability of staff
- Target number of participants
- Clinical risk score and mitigation
- Adequate funding
- Budget
- Additional training requirements
- Extraordinary monitoring/audit requirement
- Data requirements
- Equipment and storage
- Archiving

Once all discussions have taken place and GCRF management have agreed to support the study, Form 57.010C will be submitted to R&I to confirm GCRF Manager sign-off. For those studies requesting GCRF room use only, Form 57.010D will be sent to the PI and non-GCRF study team. GUI 57.010H describes the process for PIs who have not worked with GCRF previously, to gain access to research systems and training.

3.5. Local Information Pack (LIP)

Once selected as a site the sponsor/Chief Investigator (CI) will submit LIP to sites including the Organisation Information Document (OID) and OID appendix for completion of local details. GUI 57.010D describes the LIP completion and submission process to local R&I.

3.6. Site Initiation Visit (SIV)

The SIV should take place following R&I approval and prior to Sponsor Green Light. The study sponsor will arrange a date for all parties, once confirmed a suitable room should be booked. All members of the study team should be available, and should read through the protocol highlighting areas for further clarification during the visit.

The Investigator Site File (ISF) may be received in advance of the SIV; all documents received must be filed appropriately according to the ISF index. There may be instances where the ISF is not provided by the sponsor, in this case the file should be set-up using GUI 57.011A.

During the SIV the following may be discussed:

- Protocol and procedures, inclusion/exclusion criteria, additional training requirements, data and sample collection.
- Study documentation – ISF and approvals where available.
- Delegation and training log should be completed and signed by each member of the research team and countersigned by the PI.

Form 57.010B should be completed during the SIV and signed by sponsor representative and the PI.

At the end of the visit a report/checklist may be submitted to site by sponsor. The report/checklist may detail outstanding actions that arose from the SIV. The Study Team must make every effort to address these actions promptly. The SIV date, time spent and attendees must be recorded in the finance tab of the EDGE study record.

3.7. Localising study documentation

Following GUI 57.010E participant facing documents must be presented on NHS Greater Glasgow & Clyde headed paper:

- Participant Information Sheet (PIS)
- Informed Consent Form (ICF)
- GP Letter
- Any other document at Sponsor request

3.8. Creating and implementing study source data worksheets

Source data worksheets may be required if direct source data entry are not available. GUI 57.010G must be followed to create and implement source data worksheets.

3.9. R&I Permission and Sponsor Green Light

Once R&I Permission and Sponsor Green Light received, Form 57.010E, PI Support Letter, will be updated with the relevant information and sent to the Principal Investigator confirming GCRF support

and to be filed in the Investigator Site File. Recruitment can begin once the PI Support Letter is received.

3.10. Notifying Switchboard

NHS GG&C switchboard should be notified of the out-of-hours contact for if required by the study protocol following GUI 57.010F.

4. Referenced documents

- Form 57.010A – GCRF Study Support Form
- Form 57.010B – GCRF Site Initiation Visit Checklist
- Form 57.010C – GCRF Capacity Confirmation
- Form 57.010D – GCRF PI Support Letter
- Form 17.048A – Clinical Risk Assessment
- GUI 57.010B – GCRF Planning Meeting
- GUI 57.010C – GCRF Capability
- GUI 57.010D – OID Completion and Submission
- GUI 57.010E – Localising Study Documentation
- GUI 57.010F – Out-of-hours Switchboard Contact
- GUI 57.010G – Creation and implementation of study source data worksheets
- GUI 57.010H – GCRF New PI Process

5. Related documents

- SOP 57.006 – PI Responsibilities
- SOP 57.005 – Hosted Study Documentation and Data Management
- SOP 17.048 – GCRF Risk Assessment and Mitigation
- NHS Scotland Code of Practice: Protecting Patient Confidentiality (Revised 2012)

6. Document history

Version	Date	Description
1.0	21/05/2018	First release
2.0	26/08/2019	Changes from Site Specific Information form to Local Information Pack, removal of Information Systems Assistant role
3.0	18/10/2023	Update to SOP template v2.0 Addition of RACI matrix Addition of GCRF support letter process GUI 57.010A Notification and Adding Study to EDGE obsolete Update of title from SSI to OID for GUI 57.010D Addition of GUI 57.010G and Forms 57.010C and D, E Addition of Form 57.005B and C
4.0	13/05/2024	Change of author Addition of GUI 57.010H