SOP number	**57.011**	Version	**3.0**
Title	**GCRF Study Management**		

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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			
GCRF Manager		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 describes the responsibilities and activities of research study management.

3. Procedures

3.1. Responsibilities

The PI and study team have numerous duties responsibilities during the course of a research study, SOP 57.006 details the PI responsibilities. There are a number of duties which may be delegated to appropriately trained and qualified members of the study team at site initiation as detailed in the study delegation log.

3.2. Essential Documents

The maintenance of an Investigator Site File (ISF) is necessary for effective management of research studies during start-up, throughout the conduct and after the study is complete, demonstrating compliance with protocol and Good Clinical Practice (GCP) regulations.

It is important to maintain essential documents for each research study for quality check, monitoring, audit and regulatory inspection purposes.

The following guides assist the maintenance of essential documents:

- GUI 57.011A – Investigator Site File
- GUI 57.011B – Amendment Implementation
- GUI 57.005B – GCRF Archiving Process

3.3. Participant Screening and Recruitment

Informed Consent SOP 17.012 or SOP 17.055 must be followed when obtaining consent/assent from research participants. SOP 57.005 must be followed when documenting consent visit in source.

Recruiting of participants and the visit schedule must be conducted in accordance with study protocol and performed by trained and delegated members of the study team.

The PI and study team are responsible for keeping record of participants who are screened, fail screening, recruited and withdrawn from the study using the appropriate paper or electronic logs.

All participants must be recorded on EDGE Clinical Research Management System following GUI 57.016G.

3.4. Meetings

There are regular Operational Group Meetings for each GCRF specialty, frequency of these may vary. EDGE specialty recruitment and study status reports are presented at the meetings, each study is discussed and any issues raised i.e. study not recruiting to time and target.

The study sponsor or contracted research organisation may arrange annual investigator meetings, giving an opportunity to meet other sites and discuss the progress of the study. The PI is responsible for disseminating this information to the study team.

The study team must hold regular meeting to discuss trial progress, topics for discussion may include study amendments, delegation of duties, training, recruitment strategy, data quality, data lock etc. Evidence of these meetings must be formally documented, this can be an email to the attendees filed in the ISF.

3.5. Amendments

During a study it may be necessary for the sponsor to update the protocol, participant facing documents and Investigator Brochure as new information becomes available i.e. safety measures or regulatory updates.

It is the sponsor's responsibility to submit amended documents for approval (HRA, R&I, and Regulatory Authority). Sponsors may insist an amendment is implemented after 35 days, GUI 57.011B must be followed when notified of an amendment.

3.6. Safety Reporting

The PI and study team must ensure all adverse events are reported as per study protocol and within the regulated timelines. All safety reports received from sponsor/CRO are acknowledged within timelines and are filed in the investigator site file (ISF). In the instance safety reports are received through electronic portal a report can be requested from sponsor/CRO for the ISF.

3.7. Clinical Results and Reports Management

All results must be reviewed by clinician within reasonable timeframe. Many studies have both local and central laboratory processed samples, both local and central labs must be reviewed and signed-off by PI and or delegated clinician. Local laboratory results can be reviewed and signed-off within TrakCare. Central laboratory results may have an electronic review and sign-off function within the system, confirmation and instructions can be found within the laboratory manual. If electronic review and sign-off is not available, results must be printed, reviewed and signed and dated by the PI and or delegated clinician.

Abnormal clinically significant results and reports must be investigated as soon as possible and all action documented in participant electronic health record. The protocol may require clinically significant results to be reported as an adverse event.

Abnormal results and reports which are not clinically significant must be clearly documented in source and the electronic health record.

3.8. Financial Milestones

Financial milestones are agreed with Sponsor at the start of study. This information must be captured on EDGE to invoice sponsors for commercial studies the cost will be imported to edge using GUI 57.016C/D.

3.9. Study Handover

It is the responsibility of the PI to communicate to NHS GG&C Research & innovation Department and study sponsor if they are to leave their current post, long-term absence (maternity, sabbatical) and have no further involvement in the study. When there is a change of GCRF study lead nurse Form 57.011A must be completed and meeting arranged. The PI must be kept informed of changes to staff and ensure the delegation log and training logs are kept up-to-date authorising changes.

3.10. Study Close-out

Sponsor will notify sites of a study closing, a workflow is initiatied on EDGE for the study team to work through including pharmacy and finance to ensure all necessary close-out steps have been performed. A close-out visit will be arranged with the sponsor/CRO to ensure all data queries are

answered, monitoring/audit actions have been resolved, the study database is locked and all essential documents are ready to be archived.

4. Referenced documents

- SOP 57.006 – PI Responsibilities
- GUI 57.011A – Investigator Site File (ISF)
- GUI 57.011B – Site Study Amendments
- GUI 57.016G – EDGE Minimum Dataset
- Form 57.011A – Study Handover
- Form 57.011B – Amendment Tracker
- Form 57.011C – Protocol Deviation Log
- GUI 57.005B – GCRF Archiving Process

5. Related documents

None

6. Document history

Version	Date	Description
1.0	11/12/2017	First release
2.0	26/08/2019	Minor changes to process, addition of electronic health record systems CareVue and Metavision, inclusion of Source Data Agreement, inclusion of AWI exception for continuing consent.
3.0	03/02/2020	Addition of Clinical Fellows; telephone calls; QC of data; Scanning to Portal; remove reference to chapter 53 and 56; inclusion of GUI 57.011A and Form 56.002.
4.0	24/11/2023	Update to GCTU SOP template v2.0 Addition of RACI matrix Reference to SOP 17.012 and SOP 17.055 Minor changes to wording Addition of Source Data Review (SDR) Addition of amendment tracker and deviation log