SOP number	**57.006**	Version	**4.0**
Title	**GCRF Principal Investigator Responsibilities**		

Prepared by	Helen Hart
Approved by	Lynn Prentice
Released by	Jesse Dawson

SOP category	NHSGGC Clinical Research Facility – Administration

Staff category

Staff Category	**R**	**A**	**C**	**I**
Nursing	X			
Administration	X			
Clinical Research Fellow	X			
Local Clinical Trials Pharmacy	X			
GCRF Manager		X		
Principal Investigator	X			
GCRF Associate Director	X			
Senior R&I Manager				X

1. Scope

This SOP applies to all Principal Investigators of studies where Glasgow Clinical Research Facility (GCRF) is supporting the host research location.

2. Purpose

This purpose of this SOP is to describe the role and responsibilities of a Principal Investigator (PI) for research supported by the GCRF team.

The PI will be an individual who has the relevant contractual status, qualifications and experience to undertake research in NHSGGC. The PI is the person designated to take overall responsibility for the conduct and reporting of the research study at their location.

The PI must ensure the study is set-up, conducted, documented and reported according to research protocol, relevant local and study SOPs, Good Clinical Practice (GCP) and appropriate regulatory requirements.

3. Procedures

The PI has overall responsibility for the conduct of the research at their location and is accountable to Sponsor and NHSGGC

The PI must read and acknowledge all appropriate GCRF Standard Operating Procedures and attend GCP updates as required. The PI is responsible for ensuring:

GCP

- The research team gives priority at all times to the dignity, rights, safety and well-being of the participants.
- The research study team understands the legal and ethical requirements, and is familiar with the appropriate standard operating procedures and policies relating to research.
- The study complies with all legal and ethical requirements.
- Staff are aware of their legal duties when working on a Clinical Trial of an Investigational Medicinal Product (CTIMP) and Clinical Trial of a Medical Device.
- The research is conducted to the GCP and/or Research Governance Framework principles.
- Laboratory tests associated with the study as described in sponsor laboratory manual or equivalent are managed and operated to standards commensurate with national accreditation (UCAS) and/or Good Laboratory Practice (GLCP).

Delegation of Responsibilities

- The roles and responsibilities are identified and assigned appropriately to ensure the safe and effective management of the research.
- Steps are taken to assure appropriate completion of delegated tasks (GUI 57.006A: PI Oversight Plan).
- Each member of the research team is qualified, trained and experienced to undertake the delegated duties.
- Investigational Medicinal Product accountability at location.
- The research team follows protocol, unless urgent safety measures are necessary.
- Delegation of duties is transferred to a suitably qualified and protocol trained registered professional when required for extended periods of leave. It is good practice to have a suitably qualified ad protocol trained Sub-Investigator on the delegation log in case of unplanned leave.
- Where the PI delegates responsibilities to the research team, this is clearly documented in a delegation of authority and signature log. The PI remains accountable for the research study delivery.

Research & Innovation (R&I)

- Local R&I Permission is obtained and where appropriate Sponsor Green Light received prior to commencing the study.
- Relevant local R&I permission is received for changes to the protocol and/or study documentation prior to implementation, with the exception of urgent safety measures.

Safety Reporting and Data Management

- When a study involves participants under the care of another practitioner, the practitioner is informed of their participation.
- Participant's GP is informed of inclusion in study.
- Serious Adverse Events are recorded and reported to Sponsor in accordance with protocol.
- The Investigator Site File is maintained and kept inspection ready at all times.
- Data collected is of high quality, and the integrity and confidentiality of data is maintained during processing and storage.

- Research findings, once established, are disseminated promptly and fed back as appropriate to participants.
- There are appropriate arrangements to archive the data when the research has completed.
- All data and documentation relating to the study are available at the request of regulatory inspectors, monitors and auditors.

4. Referenced documents

- GUI 57.006A – PI Oversight Plan

5. Related documents

- N/A

6. Document history

Version	Date	Description	Retrospective Implementation
1.0	18/04/2018	First release	No
2.0	26/08/2019	Minor changes and inclusion of All GCRF staff in Staff Category	No
3.0	28/09/2022	Update to staff categories: GCRF supported Principal Investigators and study team GCRF Clinical and Administration	No
4.0	10/04/2026	Addition of RACI Matrix Minor typographical changes Change of author/approver	No