SOP number	**57.014**	Version	**2.0**
Title	**GCRF Support of Early Phase Clinical Trials**		

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Approved by Signature	Lynn Prentice Date
Released by Signature	Jesse Dawson 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			
GCRF Manager		X		
Site Clinical Trials Pharmacy				X
GCRF Associate Director				X
Senior R&I Manager				X

1. Scope

This procedure applies to all Glasgow Clinical Research Facility (GCRF) staff and GCRF supported Principal Investigators and study teams.

2. Purpose

The purpose of this SOP is to describe the conduct of early phase clinical trials, roles and responsibilities within GCRF. SOP 57.010 should also be followed to set-up a trial within GCRF.

3. Procedures

3.1 Feasibility

Enquiries and/or applications to conduct an Early Phase Clinical Trial in GCRF must be referred to the specialty Research Nurse Manager, Lead Nurse and GCRF Manager for consideration. The Principal Investigator together with the Lead Trial Nurse must complete the GCRF Clinical Risk Assessment Form 17.048A and submit to the specialty Research Nurse Manager, Lead Nurse and GCRF Manager along with completed Form 57.010A, trial protocol and any other pertinent information.

The specialty Research Nurse Manager, Lead Nurse and GCRF Manager will meet with the Principal Investigator, Clinical Trial Pharmacist and GCRF Clinical Director (or depute) to discuss operational and risk mitigating measures required.

3.2 Application to NHS GG&C Phase I Committee

An application for every first in human or high-risk phase I/II trial should be submitted to the NHS GG&C Phase I Committee for review. NHSGGC R&I Governance team should be contacted in the first instance for the application process. The PI should submit the application to the relevant research nurse manager for review, before submission to Phase I Committee, ensuring that the GCRF Manager and R&I Director are aware.

A request for further information may be required. The PI and Lead Trial Nurse should submit to the Committee within a reasonable timeframe. The Committee will notify the PI of the decision.

If the study includes a Genetically Modified Organism (GMO), it should be submitted to the GMO committee prior to submission to Phase I committee.

3.3. Set-up

The NHS GGC Phase I Committee will notify the PI of any conditions of approval which need to be met in the set-up phase.

Once all approvals have been sought i.e. R&I, Ethics and Regulatory Authority, early phase documents must be completed. Follow GUI 57.014A to notify ICU of early phase trial. Forms 57.014A, 57.014B and 57.014C must be completed ready for the trial to begin.

3.4. Amendments

The PI and Lead Trial Nurse must ensure that any protocol amendments are submitted to GCRF Manager and Lead Nurse for review as they may impact on the risk assessment.

3.5. Day of IMP Administration

Dosing area emergency checks and Form 57.014D Early phase IMP administration checklist must be completed.

Form 57.014C verification sheet must be completed by each member of the trial team. It is essential that it is documented each time a member of the team attends / leaves the department. The Lead Trial Nurse and PI must ensure all members of staff have recorded shift end once dosing complete and participant discharged.

4. Referenced documents

- SOP 57.010 – Study Planning, Set-up and Start-up
- GUI 57.014A – ICU Notification of Early Phase Trial
- Form 57.014A – ICU Notification of Early Phase Clinical Trial
- Form 57.014B – Early Phase Clinical Trial Contact Sheet
- Form 57.014C – GCRF Study staff support log
- Form 57.014D – Early Phase IMP Administration checklist
- Form 17.048A – GCRF Study Risk Assessment Form

5. Related documents

None

6. Document history

Version	Date	Description
1.0	20/12/2018	First release
2.0	25/09/2025	Updated to SOP template 2.0 Change to author and approver Addition of RACI Clarification of process for GMO applications Addition of new form 57.014D