Standard Operating Procedure			57.014
GCRF Support of Early Phase Clinical Trials			
Version	**1.0**		
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1. SOP Category

NHS GG&C Clinical Research Facility - Clinical

2. Staff Category

GCRF Clinical and Administration
GCRF Supported Principal Investigator and study teams

3. Scope

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

4. 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.

5. Procedures

5.1. 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 SOP 17.048 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.

5.2. Application to NHS GG&C Phase I Committee

An application for every first inhuman or high risk phase I/II trial should be submitted to the NHS GG&C Phase I Committee for review. NHS GGC R&D Governance team should be contacted in the first instance for the application process. The PI should submit the application to GCRF Manager and R&D Director for review, before submission to Phase I Committee.

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.

5.3. 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&D, 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.

5.4. 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.

ICU must be notified of any changes to the trial team and the contact sheet Form 57.014B updated accordingly.

5.5. Dosing Day

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.

6. Referenced documents

- SOP 57.010 – Study Planning, Set-up and Start-up
- GUI 57.014A – ICU Notification of Early Phase Clinical Trial
- Form 57.014A – ICU Notification of Early Phase Clinical Trial
- Form 57.014B – Early Phase Contact Sheet
- Form 57.014C – Early Phase Verification Sheet

7. Related documents

None

8. Document History

Version	Date	Description
1.0	20/12/2018	First release