SOP number	**57.015**	Version	**1.0**
Title	**GCRF Clinical Research Training**		

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SOP category	Glasgow Clinical Research Facility – Administration

Staff category

Staff Category	**R**	**A**	**C**	**I**
GCRF Nursing	X			
GCRF Administration	X			
GCRF Clinical Healthcare Support Worker	X			
GCRF Principal Investigator	X			
GCRF Information Manager	X			
GCRF Quality Lead	X			
GCRF Lead Nurse	X			
GCRF Manager	X			
GCRF Associate Director	X			
Project Management Unit	X			
Clinical Research Imaging Facility	X			
Education & Quality Lead		X		

1. Scope

This standard operating procedure applies to all Glasgow Clinical Research Facility (GCRF) staff, Principal Investigator and study teams supported by the facility.

2. Purpose

This SOP describes the processes to ensure those teams involved in clinical research are demonstrably qualified by education, training and experience to perform clinical research roles and responsibilities. To ensure new research staff members are appropriately inducted and are able to produce evidence of such training. To ensure continuous ongoing training of research staff to maintain and improve knowledge and skills.

- Detail the GCRF programme – internal and external courses (definition of 'course' also applies to workshop and presentation).
- Detail the core and extended competencies, training and evidence for specific research roles

3. Procedures

3.1 GCRF Staff Induction and Training

Appropriate welcome information will be provided to new staff by their line manager, based on Welcome Information Packs for the relevant staff group. The education and quality team will ensure the welcome information reflects current NHSGGC and legislative requirements

To induct staff to the facility, Form 57.015A must be followed for both GCRF and non-GCRF staff.

It is the responsibility of each line manager to implement formal training plans that have been tailored to the individual needs of the clinical research personnel and their role. It is recommended the formal training plan covers key training requirements that are not only reviewed regularly by the individual but also their line manager to ensure training needs are being met.

Glasgow CRF has adopted the UKCRF Network Induction Framework to prepare for new staff and induct to facility and role. Line managers must follow this to support new staff. A series of induction training sessions are also provided by the Glasgow CRF education and quality team which must be attended, as relevant to role.

3.2 Record and evidence of training

A training record will be maintained as per SOP 50.013.

3.3 Good Clinical Practice Training

All GCRF staff will complete GCP training as per the NHS GGC good clinical practice training for staff involved in clinical research policy.

Good research practice for non-drug trials training is available as an alternative for staff who are not involved in CTIMPs.

3.4 SOP Training

SOP 50.023 must be followed to develop, release and train on SOPs.

All new GCRF staff will be provided with access to Q-Pulse and allocated SOPs that are relevant to their role. The staff member must read, understand and acknowledge these.

Principal Investigators and external study teams working with GCRF will be notified of a list of SOPs to follow when their study is being supported by the facility. It is the responsibility of the Principal Investigator to ensure these SOPs are read and understood. If required, face-to-face training can be provided by the SOP author or a delegate.

3.5 Competency Framework

Glasgow CRF has adopted the UKCRF Network competency template. Staff will complete competency assessments relevant to their roles. This will be agreed with the line manager when conducting the formal training plan, and can be supported by the education and quality team if required.

3.6 Emergency Scenario Training

Glasgow CRF has adopted the UKCRF Network Emergency Scenario Guideline to support the delivery of emergency scenario training. Staff will attend one planned and one unplanned emergency scenario per year.

3.7 Study Specific Training

The Principal Investigator is responsible for ensuring study specific training appropriate to delegated duties and job description is delivered and documented before any study activities are completed. Trial specific training should be documented as required by Sponsor.

All members of the study team must ensure they receive relevant training on the protocol and other study related documents, to allow them to perform their delegated duties appropriately. If required, retraining will be delivered following a modification to the study protocol or other changes to study procedures. Training must be maintained as necessary throughout the study.

3.8 Student mentorship

Glasgow CRF has adopted the UKCRFN Student Tool kit to support student placements in GCRF.

Clinical research placements are an opportunity to demonstrate research in practice and promote research careers.

NMC Code
The NMC Code (2018) gives clear instructions that a nurse or midwife must:

- Share their skills, knowledge, and experience for the benefit of people receiving care and your colleagues. To achieve this, you must:
    - Support students' and colleagues' learning to help them develop their professional competence and confidence.

In addition to this, the NMC Future Nurse: Standards of proficiency for registered nurses (2018) states that a registered nurse will:

- Support and supervise students in the delivery of nursing care, promoting reflection and providing constructive feedback, and evaluating and documenting their performance'.

All nurses and midwives have a responsibility to support and train students. Nurses and Midwives must be able to demonstrate an understanding of research methods, ethics, and governance, and completing a research placement is an ideal opportunity for a student to develop this knowledge.

Regulatory Requirements
SI 2004/1031 requires that

- 'Each individual involved in conducting a trial shall be qualified by education, training and experience to perform his tasks', and the MHRA GCP Guide (2012) states 'that the PI may delegate activities to appropriate members of the research team but must ensure that the member of staff holds appropriate qualification for the role'.

The MHRA GCP Guide (2012) further describes the regulators expectations for delegation of tasks in clinical trials:

- 'The need for further trial-specific training can be assessed by taking into consideration the tasks performed by the staff and assessing whether these tasks are the same as those performed for standard clinical care. If this is the case, trial-specific training and delegation of responsibilities may not always be required.'

In addition to this, students in GCRF will always be supervised by a GCP trained member of staff and will only participate in supervised research activities.

GCP training
Students are required to undertake GCP training tailored to their roles and responsibilities.

This will usually be dictated by the length of the placement and may include GCP awareness training for those on shorter placements, or full GCP for those on longer placements.

Supervision and oversight of students on research placements

1. Students will be supervised by a qualified member of research staff who has completed GCP training.
2. The students are not required to sign a delegation log. The supervising staff member delegated to the research study will countersign any documentation to demonstrate oversight and responsibility.
3. Students will undertake clinical procedures and activities suitable to their level of training and experience.
4. Students will undertake research specific activities as a training event, and will be fully supervised throughout (e.g. Protocol procedures and Laboratory work)
5. The supervising research staff member remains responsible for ensuring that the research is conducted to GCP and the protocol requirements.

3.9 GCRF Education and Quality Team

The GCRF education and quality team provide a range of courses to meet the needs of the research community. The GCRF education administrator will co-ordinate the advertising and booking of GCRF courses, distribute course materials and update GCRF attendance records. The education and quality team will manage course delivery by reviewing attendance, course evaluations and audit/inspection findings. The team will keep abreast of legislative and policy changes and update course and training materials following GUI 57.015A. If a need to develop a new course or training document has been identified, GUI 57.015A will be followed.

Glasgow Clinical Research Facility lead NHS Research Scotland Good Clinical Practice (GCP) training programme. This involves keeping abreast of legislation, ensuring updates are implemented within training programme. The Education and Quality Lead will provide continuing review and update of NRS GCP materials for NRS GCP Trainers. GUI 57.015B must be followed when delivering and reviewing the GCP programme.

4. Referenced documents

- SOP 50.023 – Management of SOPs within NHSGGC R&I
- SOP 50.013 - Setup and maintenance of training files: NHS
- GUI 57.015A – GCRF Training Course Guidance
- GUI 57.015B – GCRF GCP Training Guidance
- Form 57.015A – GCRF Induction Checklist
- NHS GGC Good Clinical Practice Training for Staff Involved in Clinical Research Policy
- UKCRFN Student Toolkit Guidelines & Tools - UKCRF (ukcrfnetwork.co.uk)
- UKCRFN Induction Framework Guidelines & Tools - UKCRF (ukcrfnetwork.co.uk)
- UKCRFN Competency Assessment Templates Guidelines & Tools - UKCRF (ukcrfnetwork.co.uk)

5. Related documents

- N/A

6. Document history

Version	Date	Description	Retrospective Implementation
1.0	27/11/2025	First release	No