

Glasgow Clinical Research Facility & Clinical Research Imaging Facility Quality Manual

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1. Introduction

The Glasgow Clinical Research Facility (GCRF) and Clinical Research Imaging Facility (CRIF) are departments with NHSGGC Research and Innovation (R&I) Directorate. This Quality Manual describes delegated and assumed responsibilities for research governance and quality as per R&I Quality Manual QM-RI-1.

The GCRF and CRIF support the delivery of clinical research projects to the highest standards of research and clinical governance. The Facilities ensure quality and safety considerations are embedded throughout, promoting a culture of continual quality improvement. The GCRF and CRIF have documented and maintained a quality management system in accordance with the requirements of Good Clinical Practice (GCP) Guidelines and all applicable regulatory requirements.

- a. Aims and Objectives of the Quality Management System
 - To ensure the safety of clinical research participants.
 - To ensure the integrity of clinical research data.
 - To ensure reproducibility of paperwork and the ability to reconstruct events.
 - To ensure compliance with applicable regulations and governance frameworks.
 - Provide evidence and assurance of quality to sponsors, clinical research organisation (CRO), investigators and regulators.

- b. Scope of the Quality Manual

This Quality Manual applies to all staff and investigators working within the GCRF and CRIF. It is every individual's responsibility to work within and adhere to current national legislation/guidelines and local policies and procedures; these are referenced throughout the manual.

- c. Definitions

Abbreviation	Definition
CAPA	Corrective Action Preventative Action
CRIF	Clinical Research Imaging Facility
CRO	Clinical Research Organisation
CSV	Computer Software Validation
CTA	Clinical Trial Agreement
CTA	Clinical Trials Authorisation
GCRF	Glasgow Clinical Research Facility
GCTU	Glasgow Clinical Trials Unit
GCP	Good Clinical Practice
IMP/NIMP	Investigational Medicinal Product/non-IMP
MHRA	Medicines and Healthcare Products Regulatory Agency
NHSGGC	NHS Greater Glasgow & Clyde
QMS	Quality Management System
QP	Qualified Person
R&I	Research and Innovation
RCB	Robertson Centre for Biostatistics

SOP	Standard Operating Procedure
WI	Work Instructions
GUI	Guidelines
QMS	Quality Management System

d. References

- ICH HARMONISED GUIDELINE FOR GOOD CLINICAL PRACTICE E6(R3) (2025) EU Directive 2003/94/EC
- The Medicines for Human Use (Clinical Trials) Regulations 2004, as amended
- The UK Policy Framework for Health and Social Care Research
- The Human Tissue Act 2004
- EudraLex volume 4,: EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use
- NHS Greater Glasgow & Clyde clinical and research governance provisions
- NHS Greater Glasgow & Clyde Good Clinical Practice Training for staff involved in clinical research. CRIF Local Rules – CT, 3T and 7T MRI
- NHS Greater Glasgow & Clyde Non-Ionising Radiation Safety Policy
- Safety Guidelines for MR Equipment in Clinical Use: MHRA, February 2021
- The Control of Electromagnetic Fields at Work Regulations, Health and Safety Executive, UK, 2016
- IRMER EP16 Exposure of Volunteers for Research Studies

2. Management Responsibility

GCRF/CRIF Clinical Director and/or Clinical Research Manager/CRIF Manager representation is on the following committees:

- Glasgow Health Science Partnership Regulatory Affairs Group (GHSP RAG)
- Glasgow Health Science Partnership Delivery Group (GHSP DG)
- Glasgow Clinical Trials Unit Management Committee
- R&I Senior Management Committee
- Glasgow R&I SOP Committee
- CRIF Working Group
- CRIF Approval Group
- ICE 7T Management Group
- NHSGGC MRI and Radiation Safety Committee
- ICE Safety Committee
- NHSGGC MRI Safety Committee
- Radiation Safety Committee

GCRF and CRIF have 4 main committees at which quality issues are discussed and reviewed.

a. GCRF and CRIF Management Committees

Committee	Members
Senior Clinical Team	Clinical Research Manager Lead Research Nurse Research Nurse Manager(s) Education & Quality Lead Education & Training Practitioner Quality Assurance Lead Research Administration Manager Senior Project Manager Information Manager
SOP Committee	Clinical Research Manager Lead Research Nurse Senior Research Nurse/Midwife Research Nurse/Midwife Senior Research Administrator Quality Assurance Lead Project Site Manager CRIF Manager Imaging Data Manager Project Assistant (GCRF & CRIF)
GCP Compliance Committee	Clinical Research Manager Research Governance Manager R&I QA Lead Lead R&I Pharmacist Quality Assurance Lead Principal Investigator Representative Education & Quality Lead CRIF Manager Research Nurse Manager Representative
Education, Training & Quality Team	Education & Quality Lead Education & Training Practitioner Clinical Research Educator Quality Assurance Lead Quality Assurance Officer Clinical Research Manager Education & Quality Administrator
Health and Safety Committee	Clinical Research Manager Lead Research Nurse Research Nurse Manager(s) Education & Training Practitioner Quality Assurance Lead Research Administration Manager Senior Research Nurse Research Nurse Project Assistant CRIF Manager Senior Research Radiographer

b. Management Review

GCRF and CRIF Management Committees take responsibility for the GCRF and CRIF quality management system (QMS) by regularly including feedback opportunities through meeting agendas or by commissioning regular reports in various areas, some of these are:

- Follow-up actions from previous management reviews
- Results of Internal Audits
- Results of External Audits/Monitoring
- Participant and facility user feedback and complaints
- Status of deviation reports and CAPA projects
- Recommendations for improvement

All GCRF and CRIF staff have responsibility to report any areas of concern they have relating to the quality system to their line managers and the QA team.

c. Resources

The GCRF and CRIF Management Committees are committed to resource the quality management system to meet regulatory requirements and to maintain and improve the effectiveness of the quality management system and its processes.

I. Premises

Each facility provides and maintains an adequate infrastructure needed to provide service to users and conform to required regulations including:

- Buildings, workspace and associated utilities
- Process equipment (both hardware and software)
- Support Services (i.e. communication, etc.)

II. Staff

- GCRF and CRIF employ a team of core staff who have been selected and trained to ensure that they have the right qualifications, skills and competencies to carry out their roles. All staff have defined job descriptions.
- Staff are actively encouraged to undertake professional development courses and attend conferences and seminars to ensure that their skills are continuously developed and updated.

III. Work environment

GCRF and CRIF shall determine and manage the work environment, ensuring that the workspace is suitable for all staff.

IV. Organisational Chart

An organisational chart demonstrates reporting lines in the GCRF (figure 1) and CRIF (figure 2). The organisational chart is maintained by the quality representative and approved by senior management. The chart is updated when required.

3. Document Control

The QMS has documented procedures to control and manage processes associated with the operational and administrative procedures within the GCRF and CRIF. As part of R&I, GCRF and CRIF have implemented Q-Pulse, a Quality Management System tool to support with document control and management.

3.1. Documents

The QMS includes the following documents:

- Documented GCRF and CRIF Quality Aims and objectives.
- Documented standard operating procedures (SOPs) to ensure the effective planning, operation and control of GCRF and CRIF processes.
- Documented mandatory Guidance Documents (GUI) to detail how specified work should be carried out to ensure a systematic approach.

The GCRF and CRIF has an approved index of all SOPs and guidance documents governing its processes. All SOPs and guidance documents are approved and released on Q-Pulse QMS tool, then published on Glasgow Clinical Trial Unit website, which can be accessed by all staff and facility users of GCRF and CRIF. The master list of category headings and SOP numbers will be contained in Q-Pulse, maintained by the GCRF and CRIF QA team. The GCRF and CRIF take ownership of preparing, amending and maintaining SOPs following SOP 50.023.

3.2. Change Control

A system is in place to ensure that the latest copies of all documents are available readily to ensure effective functioning of the GCRF QMS. There is also a documented process used to ensure that changes to the system are introduced in a controlled and coordinated manner and to ensure that changes are appropriately controlled, documented and approved by designated functions, refer to SOP 50.023.

3.3. Retention of Records

Records are maintained in order to provide evidence of conformity to the requirements listed in section 1c, and of the effective operation of the QMS. GUI 57.005B details the storage, protection, retrieval, retention time and destruction of the GCRF and CRIF clinical research records.

3.4. Deviation Reporting and CAPA

The GCRF and CRIF take action to investigate the root cause of non-compliances and deviations to correct and prevent recurrence, following GUI 57.003A. Line Managers are responsible for the quality of work carried out within their team and for escalating any quality issues to the Senior Clinical Team, if applicable CRIF Manager and Quality Assurance Lead.

4. Risk Management

4.1. Risk Assessment Procedure

GCRF and CRIF staff assess the level of clinical risk for each study taking place in the facilities. The risk assessment score is derived from calculating the probable consequence and likelihood of an adverse event, potentially triggering contingency planning to detect and address issues from the outset. The robust clinical risk assessment process is detailed in SOP 17.048 for GCRF studies and SOP 58.005 for CRIF studies, ensuring risks are identified and mitigation is in place.

GCRF and CRIF follow NHSGGC Health & Safety policies, to ensure a safe environment for patients, staff and facility users.

4.2. Study Support

When study is identified in each facility the following SOPs are followed:

- GCRF follow SOP 57.010 Study Planning, Set-Up and Start-Up
- CRIF follow SOP 58.004 Clinical Research Involving Imaging.

All GCRF studies are discussed at the GCRF planning meeting where the resource required for delivery is assessed, including workforce, skill mix, data management, equipment and facility use.

5. Training

GCRF and CRIF ensure that all staff working in the facility are appropriately qualified and have received adequate training to enable them to carry out their duties and the duties delegated to them.

5.1. Staff Induction

Staff complete an NHSGGC induction, and a GCRF and CRIF clinical research induction appropriate to their role is completed. Staff qualifications and registration are checked at interview, and training needs assessed during induction. Staff are provided with the list of SOPs and supporting documents they must be trained before they can start work on their duties and studies, following SOP 50.023.

5.2. Training File Maintenance

Individual staff are required to keep a training file that includes their CV, job description, training certificates etc. in line with SOP 50.013.

5.3. Training Competency

Each manager in GCRF and CRIF is responsible for ensuring that training and resources are available to enable staff to be competent for their specified role. Staff training in some areas will require a competency assessment to provide evidence of competency. Competency assessments will be completed in line with SOP 57.015, CRIF competency assessments are stored within Diagnostics Q-Pulse, reviewed annually.

5.4. Quality System Training

All staff are required to read and comprehend this manual and the associated SOPs for their job role SOPs on Q-Pulse.

5.5. GCP Training

GCP training is mandatory for all staff working in GCRF and CRIF – this training must be refreshed every two years following NHSGGC Good Clinical Practice Training for staff involved in clinical research. Staff are responsible for ensuring that details of GCP and other essential training are recorded, and certificates filed in their training record.

5.6. External personnel

The GCRF and CRIF are responsible for ensuring that any external personnel working with/in the facility comply with relevant regulations, and complete GCRF/CRIF Site Induction prior to starting activities.

5.7. Emergency Scenarios

Staff will have their life support skills tested regularly with Emergency Scenarios. Following SOP 57.015, there are planned and unplanned scenarios scheduled annually across GCRF and CRIF.

6. Investigational Medicinal Products (IMPs)

The use of all IMPs in a clinical trial is covered by a protocol approved by the MHRA. All clinical trials must have full R&I approval prior to IMPs being received onsite from the Sponsor.

6.1. IMP Receipt

As per MHRA guidance, the receipt and storage of IMP is delegated to the Pharmacy Department. Clinical Trials Pharmacy are responsible for ensuring that IMP have been manufactured, handled and stored according to GMP (EU Directive 2003/94/EC), that each batch has been certified by the Sponsor's QP and that labelling complies with the UK Clinical Trials regulations (Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025). Clinical Trials Pharmacy SOPs for CTIMPs are within Chapter 22 of the R&I QMS.

6.2. Temperature Mapping and Monitoring

All IMPs have instructions for storage with specified temperature ranges. All IMPs are stored in secure, temperature monitored locations to ensure that the temperature range specified is not breached. In the event of a temperature deviation, the following SOPs are in place and are followed: refer to SOP 17.006. GUI 17.006 A, B, C, SOP 22.008 and GUI 22.008A, B, C, which details the actions required to ensure equipment is commissioned, calibrated and how temperature monitoring should be documented. Details are also included to cover the actions to be taken in the event of temperature deviations, and arrangements for out-of-hours actions/quarantine.

6.3. Accountability

Accountability of all IMPs (and NIMP where appropriate) is recorded at all times, ensuring that adequate reconstruction of IMP and NIMP movement is documented. This is achieved by following SOP 22.006 (Development and maintenance of the Pharmacy Dispensing and Study Management Procedure for studies hosted by NHSGGC).

6.4. Handling of non-conforming IMP held within GCRF

Any non-conforming IMP that is held within GCRF is quarantined locally or returned immediately to the Pharmacy Department, as per SOP 17.032 ensuring no product is used. The Clinical Trials Pharmacy team, Sponsor and Research team are notified of the non-conformance and the non-conformance is logged and followed up by Pharmacy in conjunction with the Sponsor. IMP may only be removed from quarantine with Sponsor's approval.

7. Equipment

All GCRF and CRIF equipment is purchased and commissioned according to NHSGGC policies. Study specific equipment is provided by sponsor and where applicable, SOPs should be followed. Only suitable trained personnel have access to GCRF and CRIF equipment, and this training/competency assessment is documented within study specific training and/or individual training records.

a) Equipment Introduction

Where applicable the equipment is:

- Subject to risk assessment.
- Given a unique identifier for traceability and record keeping.
- Validated.
- Calibrated against manufacturer standards.
- Maintained.
- Safeguarded from adjustments that would invalidate results.
- Protected from damage and deterioration during handling, maintenance and storage.
- Kept clean and fit for use.
- Decontaminated and decommissioned.

b) Risk Assessment

- Where applicable, equipment within the facility is subject to a risk assessment, as per NHSGGC policy, to assess impact on patients and trial data.
- Potential safety issues are identified, and suitable procedures are implemented and documented to mitigate these risks.

c) Fridges and freezers

- Fridges and freezers within the facility are temperature monitored according to SOP 17.006.
- A schedule for fridge and freezer cleaning and defrosting is set according to SOP 17.006.

d) Calibration and maintenance

- All equipment is subject to mandatory testing (for example PAT testing) according to NHSGGC policy.
- Where appropriate, equipment must be calibrated and regularly maintained to ensure it is fit for use. Ordinarily, the schedule for maintenance and calibration will be according to the manufacturer's instructions.
- Evidence of maintenance and calibration visits must be maintained.

e) Validation

- All equipment must be fit for purpose, and as a minimum this requires records of installation and regular maintenance by qualified person.
- For specialist equipment, a process of validation must take place according to Sponsor, manufacturer and NHSGGC policy

f) Laboratory equipment must be maintained according to Sponsor, manufacturer and NHSGGC policy. Identification and traceability

- All equipment must be allocated a unique identifier, and this must be displayed on the equipment.
- A comprehensive log of all equipment in the facility must be maintained, including details of the supplier, date received, serial numbers, as well as calibration and maintenance details.

g) Decommissioning of equipment

Any equipment that is no longer required or is faulty must be decommissioned according to NHSGGC policy or manufacturers process.

h) Patient Safety Alerts

GCRF and CRIF can be notified of patient safety alerts by Health Services Scotland, Scottish Government and study sponsors. Safety alerts are disseminated to all GCRF and CRIF staff.

i) Equipment alerts

CRIF can be notified of equipment safety notifications by imaging manufacturers. Safety alerts are disseminated to all CRIF staff and NHSGGC Physics team members and acted upon as required.

8. Audit

8.1. Internal Audits

- I. Internal audits will be conducted to verify that each GCRF quality system is in compliance with the established GCRF and regulatory requirements and to verify the effectiveness of each system (SOP 57.003).
- II. The QA Lead will develop and administer an agreed annual internal audit schedule in the GCRF. This will include implementing, scheduling, communicating, maintaining, and monitoring the schedule.
- III. An internal audit schedule will be planned and maintained with audits conducted periodically to monitor compliance with GCRF policies and procedures and regulatory requirements.
- IV. Internal audit must be performed according to SOP 57.003.
- V. Audit activities are selected according to the audit schedule and GCRF priorities and requirements and will be performed by persons who are not responsible for the area being audited. Each audit activity will be reported and will be acted upon as necessary.
- VI. The internal audit schedule and annual activity summary are reviewed each year by GHSP RAG.

8.2. Internal Audit Report

- I. An internal audit report will be created to summarise audit findings.
- II. The audit report will document the observations and findings of the components audited, with a comment and recommendations where appropriate. This report will then be issued to the personnel responsible for the area audited for review and action and for escalation to senior management as required.
- III. Findings and actions identified by audit will be documented and addressed in a timely manner with implementation of corrective and preventative actions verified and documented.
- IV. It is important that a continual review of audit findings and the management of associated corrective and preventative actions are performed to ensure continuous quality improvement.

8.3. Third Party Audit/Monitoring Findings

- I. A system will be maintained to manage regulatory inspections, third party audits and any associated responses and actions (SOP 57.008). Findings or observations identified during an inspection or audit must be responded to and resolved in a timely manner.
- II. When issues arising from a third party audit or inspection have been categorized as 3 or 4 (or major/critical), they will be escalated to R&I Governance following SOP 51.008

- III. Non-compliance identified through monitoring/audit/other will be managed following GUI 57.003A.

9. Researcher, Participant, Sponsor and Staff Feedback

9.1. Feedback

NHSGGC Share Your Feedback, allows research participants to share feedback on what works well and improve what could be better. Feedback can be discussed with GCRF and CRIF staff in the first instance.

9.2. Complaints

- I. It is important that feedback from stakeholders is part of the process for evaluating and continually improving the quality of the service provided by the GCRF and CRIF. This is in keeping with the NHSGGC Complaints Policy.
- II. Positive comments are reported back to staff and constructive feedback is used to improve our users' experiences.

9.3. Complaint Handling

The GCRF and CRIF follow NHSGGC Complaints Policy for managing complaints. Formal complaints are directed to line manager in the first instance, who investigates the issue and attempts to resolve it as quickly as possible. In the event that local resolution of a complaint is not possible, participants may contact NHS Scotland Patient Advice & Support Service.

9.4. Referenced documents

- SOP 17.006: Refrigerator and Freezer Unit Use and Monitoring
- GUI 17.006A: Out of Hours Fridge and Freezer Alert
- GUI 17.006B: GCRF Celsius Fridge/Freezer Management System
- GUI 17.006C: GCRF Checkit Fridge/Freezer Management System
- SOP 17.032: Return of Stock Drugs and IMPs
- SOP22.006 Development and maintenance of the Pharmacy Dispensing and Study Management Procedure for studies hosted by NHSGGC
- SOP 22.008: Temperature Monitoring for IMPs and Other Medicines Involved in Research
- GUI 22.008A: Environmental monitoring for IMPs and other medicines involved in research: temperature monitoring
- GUI 22.008B: Standards for Refrigerators and Freezers and Temperature Monitoring Equipment for Clinical Trials
- GUI 22.008C: Temperature Mapping for Refrigerators and Freezers used to Store IMPs and Other medicines involved in research.
- SOP 50.013: Setup and Maintenance of Training Files: NHS
- NHSGGC Complaints Policy
- SOP 50.023: Management of SOPs within NHSGGC R&I
- GUI 57.005b: GCRF Archiving Process
- SOP 57.010: Study Planning, Set-up and Start-up
- SOP 57.015: GCRF Clinical Research Training
- SOP 58.004: Clinical Research Involving Imaging
- SOP 17.048: GCRF Risk Assessment and Mitigation
- SOP 58.005: CRIF Risk Assessment and Risk Mitigation
- SOP 57.003: GCRF Internal Audit

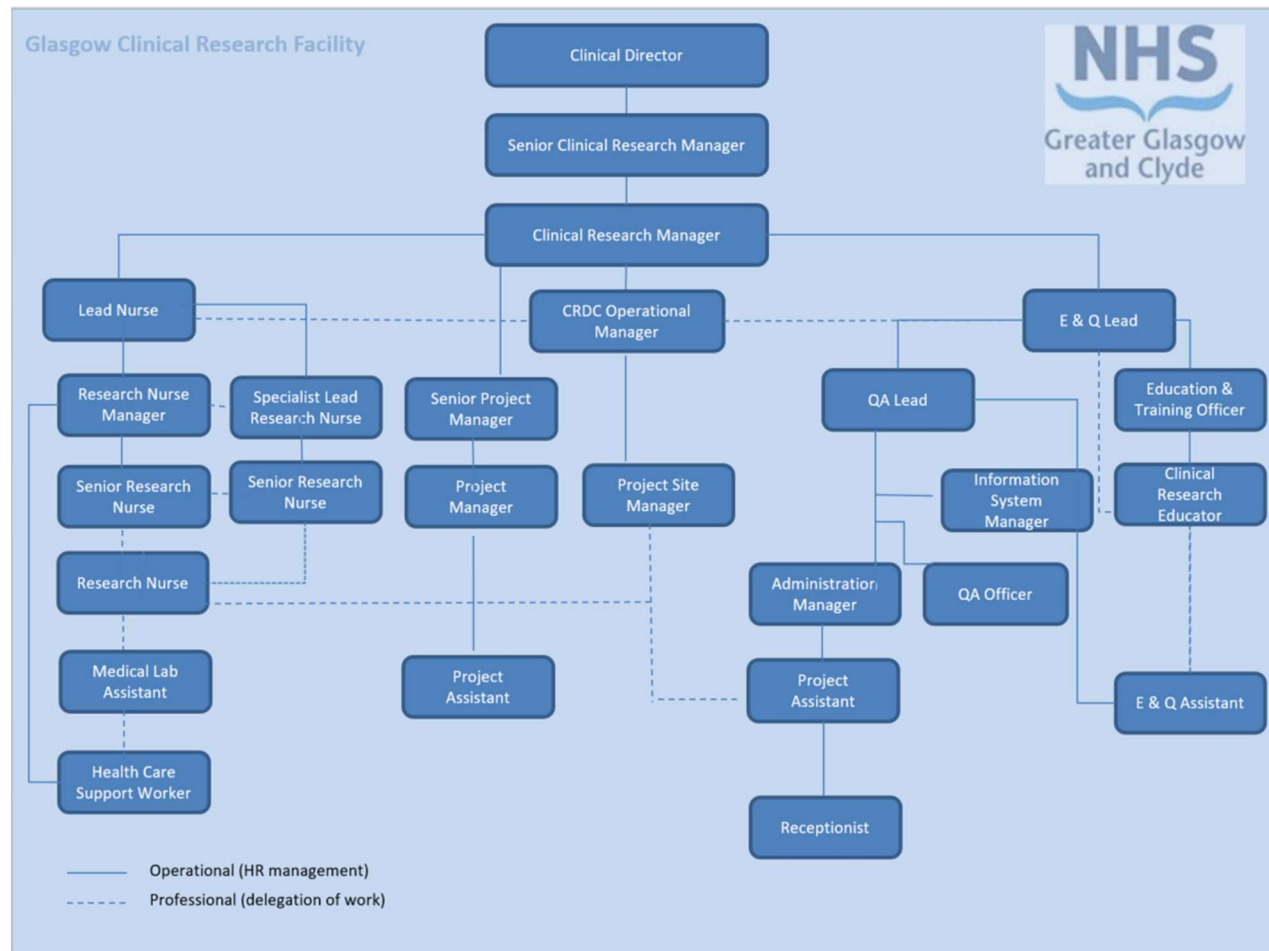
- GUI 57.003A: GCRF Non-compliance and CAPA Report
- SOP 57.008: External Audit and Inspection
- SOP 51.008: Handling non-compliance with Good Clinical Practice (GCP) and/or the trial protocol in clinical research sponsored, co-sponsored or hosted by NHS Greater Glasgow and Clyde
- QM-RI-1: R&I Quality Manual

9.5. Related documents

- NHSGGC Policies – www.nhsggc.org.uk

Glasgow Clinical Research Facility & Clinical Research Imaging Facility Quality Manual
Figure 1

Clinical Research Facility



Clinical Research Imaging Facility

