SOP number	**58.004**	Version	**3.0**
Title	**Clinical Research Involving Imaging**		

Prepared by Signature	Tracey Hopkins Date
Approved by Signature	Chloe Cowan Date
Released by Signature	Julie Brittenden Date

SOP category	58 NHS GG&C Clinical Research Imaging Facility

Staff category

Staff Category	**R**	**A**	**C**	**I**
CRIF Radiographers	X			
CRIF Project Assistant	X			
CRIF Administrator	X			
R&I Co-ordinators	X			
R&I Research Facilitators	X			
Senior Research Administrators	X			
Research Administrators	X			
Innovation Project Managers	X			
Head of MRI Physics	X			
Chief/Principal Investigator	X			
CRIF Manager		X		
R&I Systems Manager				X
Innovation Lead				X

1. Scope

This procedure applies to the R&I Systems team and Clinical Research Imaging Facility (CRIF) staff.

2. Purpose

The purpose of this SOP is to describe the research imaging delivery assessment and approval of studies conducted in NHS Greater Glasgow & Clyde during the set-up phase of imaging studies.

3. Procedures

Clinical research imaging studies will be assessed adhering to imaging/study protocol, Good Clinical Practice (GCP) and Ionising Radiation (Medical Exposure) Regulations (IRMER).

The CRIF Planning Team will consider the following during the delivery assessment:

- Staffing levels
- Training requirements
- Facility capacity
- Image data management
- Hardware and software
- Quality Assurance (QA)
- Reporting requirements
- MRI Physics team requirements

CRIF will be notified of an imaging study using Form 58.004A CRIF Imaging Support Form from the Research & Innovation Systems team. CRIF may also be contacted directly by the study Chief/Principal Investigator, Form 54.008A must be completed and submitted to R&I Systems Team. Once a draft imaging/study protocol is available, the imaging requirements can be assessed for delivery.

3.1 Staff

CRIF is responsible for ensuring all radiography staff working on a research study are available and suitably trained. The number of staff required to deliver the imaging component for each study will be assessed with current activity of the facility.

For projects that require input from NHS GG&C Physics MRI team, a further assessment and approval by the Head of MRI Physics should be obtained before confirming the study starts.

Imaging reporting arrangements must be agreed at the start of the study. CRIF must include this in the capacity assessment.

In the rare occurrence a study team should be blind to the scan results, an independent clinician, delegated by the PI, and must be named to review and report on results before the study starts. It is a PI responsibility to inform CRIF of the unblinded clinician.

3.2 Training

All CRIF staff will maintain professional registration and training records in accordance with SOP 50.013. Research study/imaging protocols must be assessed for further training requirements. All protocol training must be recorded in study training records. Relevant competencies will be completed as required by team members following SOP 57.015.

3.3 Capacity and capability

To ensure CRIF has the capacity and capability to deliver an imaging/study protocol the following must be assessed by the CRIF Planning Team, workforce requirements, active studies, support availability, reporting, scan time and number. Once capacity assessed CRIF will confirm with the R&I Systems team if the facility has the capacity to participate in the study.

3.4 Quality Assurance

Routine QA will be performed in accordance with manufacturer's guidance. QA of research procedures will be determined during the support assessment; staff and machine time must be factored in.

3.5 Imaging Activity Data Capture

All imaging requirements will be recorded on the Scottish Research Database Application (SReDA), and EDGE systems by the CRIF Project Assistant and Administrator. CRIF are responsible for ensuring all imaging activity data recorded on these systems is complete and accurate before scanning starts, and maintained until study close. CRIF activity will be reported using these systems to the CRIF Working Group and GHSP Delivery Board as required.

3.6 Risk Assessment and Contingency Planning

The risk assessment for each study will be conducted following SOP 58.005.

3.7 CRIF EDGE Workflow

A study checklist will be completed by the CRIF team by working through the study checklist worklist on EDGE. The worklist must be completed before scanning starts, and provides a documented record that the steps described in this SOP have been completed, and signed off by the CRIF Management Team.

4. Referenced documents

- SOP 58.005 – CRIF Risk Assessment and Risk Mitigation
- SOP 50.013 – Setup and maintenance of training files: NHS
- Form 58.004A – CRIF Support Form
- Form 58.005A – CRIF Study Risk Assessment
- GUI 58.004A – Imaging Studies Approval Process

5. Related documents

- SOP 58.008 – CRIF Controlled Access
- GUI 58.008A – CRIF Researcher MRI Entitlement & Authorisation Guidelines
- Form 58.008A – MRI Research Entitlement & Authorisation Application Form

6. Document history

Version	Date	Description
1.0	17/10/2016	First release
2.0	13/01/2020	Removal of reference to CRF Manager and working group in section 5.5
3.0	21/08/2023	Update to SOP Template v2.0 Addition of R&I Systems Inclusion of imaging studies approval process guidance Update of CRIF Imaging support Form

Version	Date	Description
		Removal of guidance assigning a clinical scientist

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