SOP number	**58.006**	Version	**3.0**
Title	**Reporting of Research Images**		

Prepared by Signature	Tracey Hopkins Date
Approved by Signature	Chloë 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**
Clinical Research Imaging Facility (CRIF) staff		X		
Radiologists	X			
Principal Investigator	X			
Clinical Research Fellow	X			
Clinical Physicist	X			

1. Scope

This procedure applies to all staff working within Glasgow Clinical Research Imaging Facility (CRIF).

2. Purpose

Patients, specific subject groups and healthy volunteers undergo detailed imaging as part of research projects, or for development of new imaging technologies. These scans may include diagnostic images which may inform the patients' clinical care, and occasional incidental findings in healthy volunteers may have health implications that require appropriate management.

The purpose of this document is to ensure that all imaging examinations performed for research purposes be appropriately handled, in most cases this means reported by a fully qualified radiologist.

The frequency and timelines of reporting, the diagnostic content and the wording of reports, may vary between research projects. Any *clinically-relevant* findings should be communicated to a clinically responsible individual, who can act on the information appropriately.

3. Procedures

3.1. Image reporting plan

The study protocol must state whether or not an imaging procedure conducted as part of a research protocol will produce an image that is suitable for diagnostic purposes. Study-dependent information about health-significant incidental findings should be included in the protocol and participant information. If radiology reporting of research scans is performed, this may identify incidental findings.

For many clinical studies and those studies that involve research participants, incidental findings are picked up opportunistically by imaging staff i.e. every scan is NOT read by a radiologist for incidental findings. This should be made clear in the participant information sheet and informed consent form, and discussed during the consent process.

All research projects that involve CRIF imaging will be recorded on the EDGE Clinical Research Management System. Incidental reporting requirements will be included in the project record on EDGE prior to scans being performed.
Data points include:

- The type and frequency of scans.
- When incidental finding review is opportunistic.
- The radiologist(s) assigned to the study.
- The name of a clinician who can review study images when the PI is blinded. The blinded study team may be made aware of incidental findings, depending on the study protocol.

3.2. Identifying a study radiologist

- A reporting radiologist with appropriate specialty expertise will be identified by CRIF Planning Team.
- The confirmed radiologist and their unique identifier number is recorded on the Clinical Radiology Imaging System (CRIS) database and named on EDGE**.**

3.3. Booking study-specific scans

All CRIF study scans are recorded on EDGE. Imaging appointments for NHS GG&C approved research studies will be booked in through the Clinical Radiology Imaging System (CRIS) by the CRIF administration team.

3.4. Reporting the scan

- The Form 58.004A will confirm location of the research image for radiology review e.g. NHS PACS.
- The agreed radiologist will be responsible for reporting of the research scans within an appropriate time frame or if provided, the time frame specified in the study protocol. An incidental finding may be picked up at this stage by the study radiologist.
- An incidental finding may also be picked up, either at the time of scanning or at a later review point. In this case the CRIF team will alert the study radiologist as soon as possible, preferably 1-2 working days to review the image.
- If the image is of diagnostic quality, the incidental finding report will be recorded on CRIS and form part of the participant's electronic health record. Additional diagnostic imaging may be deemed necessary by the study radiologist. The research participant will be contacted by the PI and any further imaging will be conducted by the CRIF team.
- The PI will be responsible for reviewing the report after consultation with the agreed radiologist.
- A study team may be blinded to the reporting. In conjunction with an unblinded clinician, and consistent with the study protocol and safety reporting requirements, the blinded study team may be made aware of incidental findings.

3.5. Participant referral for further clinical investigation

The PI has a responsibility to ensure the participant is referred to the appropriate NHS clinical pathway. In the instance of a non-medical PI, the reporting radiologist may advise appropriate referral pathway e.g. GP or specialist clinician.

4. Referenced documents

- GUI 58.006A

5. Related documents

None

6. Document history

Version	Date	Description
1.0	17/10/2016	First release
2.0	24/04/2019	Approved: split into two SOPs – this SOP cover identifiable images. SOP 58.007 covers anonymised images
3.0	21/08/2023	Update to SOP template v2.0 Addition of RACI matrix Update title Revised SOP to cover all reporting requirements, merged SOP 58.006 and 58.007