# Standard Operating Procedure **58.007**

# **CRIF Review of Incidental Findings (anonymised images)**

Version **1.0**

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## SOP Category

Clinical Research Imaging Facility (CRIF)

## Staff Category

CRIF staff

Radiologists

University of Glasgow (UoG) researchers conducting imaging on UoG or CRIF scanners

Chief/Principal Investigator(s)

## Scope

This SOP applies to all Clinical Research Imaging Facility (CRIF) staff and the staff groups listed above when a suspected incidental finding is identified in the conduct of a research study where the images are anonymised at the point of scanning. This SOP does not cover incidental findings from research studies conducted on a CRIF scanner where the images are identifiable at the point of scanning (see SOP 58.006). This SOP applies to imaging conducted on the CRIF NHS scanners (3T MRIS, 7T MRI and CT) as well as the UoG 3T MRI scanner and Beatson Oncology Centre 1.5T clinical scanner.

1. **Purpose**

Incidental findings are defined as observations of potential clinical significance unexpectedly discovered in research participants and unrelated to the purpose of the study. The primary purpose of imaging used in research is to answer the research question – not to provide a diagnostic service. However even when this is clear to research participants, the researchers have a duty of care to follow up any incidental finding that it is identified during the course of a research study.

Many imaging studies conducted by UoG researchers involve imaging sequences that are not clinically useful and are not stored on PACS as part of the patient record. These studies are often conducted in a university setting or using anonymised images at the point of scanning to facilitate transfer from the NHS for analysis purposes.

All research studies performed within CRIF or on the UoG 3T MRI scanner must follow the guidance plan GUI 58.007A: CRIF Review of Incidental Findings (anonymised images). CRIF staffs are responsible for ensuring the process is adhered to. Only any subsequent imaging of diagnostic quality and/or report will become part of a research participant's medical record. But relevant images from the research study that identified the incidental finding would be stored by the research team and referred to in the medical record and radiology reports.

1. **Procedures**

5.1 Imaging Incidental reporting plan

The participant information sheet must explain the diagnostic limitations of the imaging protocol and provide clear information as to how potentially health-significant incidental findings may be detected, and the follow up process. For these studies, incidental findings are picked up opportunistically by imaging staff, i.e. every scan is NOT read for incidental findings. Participant understanding of the incidental finding process should be captured in the consent process.

UoG researchers will record anonymised research imaging studies using healthy volunteers on UoG systems when they are conducted on the UoG 3T scanner. The researchers must record the participant’s GP and their Community Health Index (CHI) number.

All research projects that involve anonymised imaging using CRIF scanners will be recorded on the Scottish Research Database Application (SReDA). This is true for studies involving patients or healthy volunteers. In contrast, only anonymised studies involving NHS patients will be recorded on SReDA when imaging is conducted on the UoG 3T MRI scanner.

Data entry includes:

* The type and frequency of scans.

CI/PI in conjunction with the R&D Coordinator and/or Lead Radiographer should complete the imaging data on SReDA.

5.2 Identifying a radiologist

For anonymised studies conducted by UoG researchers on CRIF scanners or the UoG 3T MRI scanner, where incidence of incidental findings is expected to be low and identification opportunistic, a radiologist will not be assigned to the study at the outset. Instead the CRIF team will assign a radiologist from the CRIF radiology pool to assist when a potential incidental finding is reported. If the incidence of incidental findings is expected to be higher (e.g. studies in older adults or volunteers with health problems) then a study radiologist should be assigned in advance. In this case i.e. depending on the study protocol, if a large number of anatomical scans need to be read by a radiologist for incidental findings, CRIF is likely to outsource this activity to a company on the framework that provides a radiologist reporting service and charge this to the study.

Similarly, when CRIF radiographers are conducting anonymised studies where incidence of incidental findings is expected to be low on CRIF scanners, a radiologist will be assigned only at the point that a potential incidental finding is reported.

5.3 Booking the scan

With anonymised imaging, patients or healthy volunteers cannot be booked in through the Clinical Radiology Imaging System (CRIS), which requires participant identifiable information and not study identifiers. Because of this, scans are booked and recorded on separate NHS GGC and UoG systems.

5.4. Reporting the scan

* Anonymised images are not designed for clinical interpretation and are not routinely reported by a radiologist. If a suspected incidental finding is picked upby an Authorised MR Operator, it must be discussed with the site radiographer as soon as possible, preferably within 1-2 working days to review the image. Support may be requested through CRIF for a radiologist to view the anonymised image to confirm whether or not a potential incidental finding needs further investigation. However, if the rate of incidental findings is likely to be high, or the protocol specifies that all anatomical images should be reported, CRIF will outsource this activity to a company on the framework that reports anonymised images.
* If an incidental finding is suspected from the review of the anonymised scan, the UoG researchers will de-anonymise the scan to include participant identifiers such as name, CHI, sex, date of birth and address so that the scan can be uploaded through the Image Exchange Portal (IEP) to PACS for radiologist review.
* The CRIF team will assign a radiologist to review the (now) identifiable anatomical scan and decide on any further imaging requirements. If required, the PI/CI will contact the research participant to inform them about the potential incidental finding, using a script approved by NHS REC. The CRIF team will send out an appointment letter and conduct any additional imaging within CRIF. This process will be clear in the study information.
* Post scan, CRIF staff will enter all scan visits on the CRIS system and images will be sent to PACS for reporting utilising the radiologist’s number.
* The agreed radiologist will then be responsible for reporting any follow up scans within the approved timeframe of 5-10 working days.
* The incidental finding report will be recorded on PACS and form part of the participant’s medical record.
* The PI/CI will be responsible for reviewing the report after consultation with the agreed radiologist.

5.5Participant referral for further clinical investigation

* The PI/CI, or a clinician associated with the study, will agree onward referral within GGC, in conjunction with the study radiologist.
* The radiologist’s report will be forwarded to the healthy volunteer’s GP – for information.

## Referenced documents

GUI 58.007A: CRIF Review of Incidental findings (anonymised images)

## Related documents

## Document History

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| **Version** | **Date** | **Description** |
| 1.0 | 17.09.18 | Drafted |
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