SOP number	**58.009**	Version	**1.0**
Title	**CRIF Study Data and Documentation Management**		

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

The purpose of this SOP is to describe the procedures for the collection, recording and management of GGC clinical research imaging study data and associated documentation as part of the image acquisition. To manage and maintain source data assuring correct and consistent recording, transfer and storage of all imaging data; thereby enable intelligence and audit reporting.

3. Procedures

Clinical research imaging data is collected, recorded, transferred and stored in a variety of formats depending on the imaging modality and must be of the highest quality, handled appropriately and managed in accordance with information governance and research regulations.
The transfer of data should be in accordance with NHS Scotland Code of Confidentiality, Data Protection Act 1998 and NHS Greater Glasgow & Clyde (NHS GG&C) Information Governance Policies.

3.1 Source and storage of imaging data

Imaging source data is the original raw image data, usually in DICOM format, of clinical imaging research which is necessary for the reconstruction and evaluation of the study.

The study team must agree the source data plan with sponsor/CRO at study planning stage, if not provided by follow Form 56.002M. This source data plan should be stored in the CRIF site file.

PACS (National picture archiving & communication system): all clinical research scans and CRIF Approval Group development scans will be sent to NHS PACS enable review by an assigned radiologist, forming part of the subjects' electronic health record.

Additionally, for the research analysis and storage of research images, details of the requirements must be agreed prior to study start and detailed in source data and management plan (Form 56.002M).
The CRIF Data Manager (DM) will be responsible for setting up the approved source data and management plan (Form 56.002M) for each NHS sponsored study as well audit of data consistency.

CRIF staff must be trained in the source data and management plan prior to start of study by the DM.

3.2 Imaging Data Transfer

CRIF may be required to transfer images to a central imaging lab/repository. These can be transferred to a range of stakeholders utilizing a variety of imaging exchange platforms.

3.3 Image archive

The study will end as defined in the research protocol. The retention period for the research data will be defined in the study protocol.

4. Referenced documents

- Form 56.002M – Source Data Plan

5. Related documents

- SOP 58.004 – CRIF Imaging Support
- Form 58.004A – CRIF Imaging Support Form
- GUI 57.005 – GCRF Data Transfer

6. Document history

Version	Date	Description
1.0	23/11/2023	First release