Standard Operating Procedure		51.033
Research Imaging for Trials involving an Investigative Medicinal Compound (CTIMP) Sponsored by NHS GG&C or Co-sponsored by NHS GG&C and the University of Glasgow (UoG)		
Version **1.0**		
Prepared by: Roma Armstrong	Signature	Date
Approved by: Tracey Hopkins	Signature	Date
Released by: Julie Brittenden	Signature	Date

1 SOP Category

NHS GG&C Sponsor R&D

2 Staff Category

Members of Clinical Research Imaging Facility Working Group
Lead Research Radiographer
Chief Investigators
Senior R&D Managers
R&D Research Co-ordinators
NHS GG&C Sponsor Project Management Unit & Project Managers

3 Scope

This procedure applies to clinical trials of investigational medicinal products (CTIMP) sponsored by NHS Greater Glasgow & Clyde (NHS GG&C) or co-sponsored by NHS GG&C and the University of Glasgow (UoG) which involve radiological imaging. This includes trials sponsored or co-sponsored by NHS GG&C even if NHS GG&C is not a participating site or when the imaging and/or data handling is not conducted by NHS GG&C and/or Clinical Research Imaging Facility (CRIF).

4 Purpose

Analysis of radiological imaging contributes significantly to research data, including, eligibility criteria, primary and secondary outcomes and in some cases essential safety information. It is therefore essential that research imaging is performed and reported as per trial protocol, by appropriately trained and qualified radiological or other designated staff.

The research imaging may be performed locally within NHS GG&C or CRIF scanners or at other trial sites. Analysis and reporting may occur centrally or locally depending on the trial protocol. Training should be appropriate to the nature of the trial imaging protocol.

All research and NHS radiological scanners undertaking activities relating to eligibility criteria, primary, secondary or safety end-points for CTIMPs must operate in accordance with Good Clinical Practice (GCP), applicable legislation and guidance.

5 Procedures

5.1 Categorisation of Research Imaging

Prior to trial commencement any research imaging detailed within the trial protocol should be classified according to the following criteria. Form 51.033A should be completed for each imaging outcome listed within the protocol and this should be filed in the laboratory section of the Sponsor Trial Master File (TMF) and in the trial Investigator Site files detailing**:**

Category 1: Standard imaging protocol i.e. in use in clinical practice within NHS
Category 2: Standard imaging protocol, with specific requirements or
Category 3: Nonstandard imaging protocol specific to research trial

5.2 Procedures for performing and reporting imaging scans

5.2.1 Category 1 – Standard imaging protocol i.e. in use in clinical practice within NHS

These imaging procedures may be performed and reported within the local NHS scanners in the same manner as those which are part of clinical care practices within NHS. For studies sponsored by NHS GG&C or Co-Sponsored by NHS GG&C & UoG, imaging scanning procedures must be performed and processed in accordance with GCP, applicable legislation and guidance.

Where imaging conforms to routine protocols, including image analysis and reporting:

- A sponsor file note will be filed in the Sponsor TMF and within the trial Investigator Site files detailing that standard NHS processes are acceptable.
- The CRIF Working Group will be required to be informed by email about the trial.

5.2.2 Category 2 – Standard imaging protocol, with specific requirements

Examples include specific requirements for:
- Referral of patients to a specific site for imaging, e.g. CRIF
- Additional protocol-dependent imaging that uses clinical care practices but is not standard of care
- Anonymisation and archive with upload/ transfer of images
- Additional analysis of images, including anonymisation and archive with upload/ transfer of images
- Adjustments to existing imaging procedures which might otherwise compromise compliance with the protocol (for example; phoning results may be a standard procedure, but for a clinical trial sample, may result in un-blinding of the trial team).

In cases where specific requirements for performing and reporting radiological imaging scans exist which differ from routine processes:

- The CRIF Working Group will be required to be informed by email about the trial to agree that categorisation is appropriate
- The CRIF Working Group will be expected to notify sponsor if the specific requirements may adversely affect the routine imaging pathway for the patient
- A **Trial Specific Imaging Manual** (Form 51.034A) provided by the sponsor with input from the CRIF Working Group will detail the specific requirements for performing and reporting research imaging. The Trial Specific Imaging Manual should be filed in the laboratory section of the Sponsor TMF, and in the trial Investigator Imaging Site files.

5.2.3 Category 3 – Nonstandard Imaging protocol specific to research trial

In cases where non-routine care research imaging scans are performed within NHS or CRIF scanners:

- The CRIF Working Group, meets regularly, and will be required to discuss the trial imaging requirements.
- Named person(s) within the trial team will be expected to be responsible for any imaging-specific quality assurance as deatiled on the delegation log.
- A **Trial Specific Imaging Manual** (Form 51.034A) provided by the sponsor with input from the CRIF Working Group will detail the specific requirements for the research imaging. The Trial Specific Imaging Manual shall be filed laboratory section of the Sponsor TMF, and in the trial Investigator Site files.

5.2.4 NHS GG&C & UoG acting as 'Central' Imaging Centres

NHS GG&C and UoG Radiological/designated trial staff may receive and report images as a central imaging centre as specified within the protocol. The respective imaging department procedures should be adhered to whenever possible.

- The CRIF Working Group will be required to meet to discuss the trial imaging requirements.
- Named person(s) within the trial team, as recorded on delegation log, will be expected to be responsible for adherence to the quality assurance procedures specified in the trial protocol to ensure the integrity of the images, image analysis and resultant data.
- Archival of image analysis data and scans will also be specified in Form 51.034A and approved by the CRIF Working Group, with input from the CRIF Working Group will detail the specific requirements for research imaging, analysis and archiving. The Trial Specific Imaging Manual shall be filed in the laboratory section of the Sponsor TMF, and in the 'Central' Imaging Centre Site file.

5.2.5 Documenting imaging capability of potential trial sites

Depending on the categorisation of the imaging scans, not all NHS sites may have the capability required. Forms 51.033B and 51.033C provides templates of CT or MRI site survey questionnaires that can be used to identify potential participating sites.

5.2.6 Imaging Departments external to NHS GG&C

External Imaging departments performing category 3 imaging scans will be subject to vendor assessment and contracts.

5.3 Trial Specific Imaging Manual

This is required for trials which use category 2 and 3 imaging tests from above and/or are undertaking any form of central reporting function. The Manual details the processes for participating site staff to undertake research imaging, anonymisation and/or upload or transfer of acquired imaging data, reporting of imaging and archive of acquired image data including reports - as described in SOP 51.034.

5.4 Training of Imaging Staff

5.4.1 Category 1: Standard imaging protocol i.e. in use in clinical practice within NHS

Imaging departments/scanners that perform and process research scans to the **same standard** as for clinical care will have systems in place for training that will have been subjected to **review by audit and inspection**. Assuming that imaging staff are trained in these procedures

- There is no requirement to obtain CVs and GCP certificates unless there is a specific reason to do so.

5.4.2 Category 2: Standard imaging protocol, with specific requirements

There is no requirement to obtain CVs and GCP certificates unless there is a specific reason to do so. Where specific requirements for processing research images exist which differ from routine processes, these shall be subject to documented training. This information shall be included in the Trial Specific Imaging Manual provided by the sponsor. Evidence of training shall be in the form of trial specific SOP or imaging manual training records.

A named person within each imaging department/scanner must understand the role of the research imaging (its role in determining patient safety and eligibility, and in endpoint analysis) to ensure that research imaging is performed and processed in accordance with GCP, applicable legislation and guidance.

- The named responsible officer must receive applicable GCP training

5.4.3 Category 3: Nonstandard Clinical tests/'Research Specific' Tests

Where research images are contributing to trial endpoints and the research imaging performed is specific to the research trial, named imaging staff processing and reporting these samples must have:

- Appropriate GCP training to perform their delegated role.

5.5 Training Records

The imaging department shall ensure that all staff processing 'routine care' research subjects are qualified and trained to do so. Evidence of competency to conduct the required scanner/operate particular instruments shall be available for all staff in their training files held within CRIF.

Training for all staff in procedures specific to research scans and images must be recorded in their training files. The radiological staff who are responsible for the overall management of performing and reporting research scans must be able to provide evidence of training of all staff if required and must be prepared to provide a copy of their own CVs and associated training to illustrate the knowledge required for the management and oversight of research scans within the department.

5.6 NHS GG&C Clinical Research Imaging Facility Working Group

The NHS GG&C CRIF Working group includes representation from NHS GG&C Imaging Diagnostic Department & NHS GG&C Sponsor team and oversees:

- The development of the Quality Standards associated with the CRIF
- Development and deployment of processes relating to research images
- Review of deviations & non-compliances
- Identification and reporting of risks
- The planning & review of internal & external audit reports

The group reports directly to the Glasgow Health Science Partnership Delivery Board and will inform the Glasgow Health Science Partnership Regulatory Affairs Group of any significant audit findings, deviations or non-compliances.

6 Referenced documents

- Form 51.033A CTIMP Categorisation of Imaging Scans
- Form 51.033B MRI site survey template
- Form 51.033C CT site survey template
- SOP 51.034- Writing Trial Specific Imaging Manuals for Trials involving Investigational Medicinal Products sponsored by NHS GG&C or Co-sponsored by NHS GG&C and the University of Glasgow
- Form 51.034A Sponsor Imaging Manual
- SOP 56.002 – Project Management Trial Set-up

7 Related documents

- MHRA Good Clinical Practice Guide

8 Document History

Version	Date	Description
1.0	03/01/2019	Process development
1.0	22/01/2019	Reviewed by CRIF Working Group
1.0	09/03/2020	First release