University Hospitals Plymouth NHS Trust

STANDARD OPERATING PROCEDURE

DO NOT USE THIS SOP IN PRINTED FORM WITHOUT FIRST CHECKING IT IS THE LATEST VERSION

The definitive versions of all UHPNT RD&I Dept SOPs appear online, not in printed form, to ensure that up to date versions are used. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the Trust's website: https://www.plymouthhospitals.nhs.uk/research-sops

Consistency of images obtained for clinical research trials

SOP No: T13

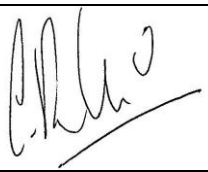
Version No: 1.1

Effective Date: Jan 2019

Supersedes: Version 1.0, Sep 2017

Page: Page **1** of **5**

Last Review Date: Jan 2019 Next review date: Oct 2022

	APPROVED BY
Name:	Chris Rollinson
Job Title:	Research Governance Manager
Signature:	
Date:	21st Jan 2019

1 Purpose and Scope

To ensure images recorded for clinical research trials are collected and recorded consistently throughout a study and that protocol procedures are followed. For a research study consideration must be given to set-up, operation and maintenance of imaging equipment to ensure consistency between images taken throughout the study.

Scope: the Superintendent Radiographer, Consultant Radiologist and imaging technicians should follow this procedure to ensure consistency when collecting research images.

Acronyms & Definitions

CI	Chief Investigator
MRI	Magnetic Resonance Imaging
UHPNT	University Hospitals Plymouth NHS Trust
PI	Principal Investigator
RD&I	Research Development & Innovation
SOP	Standard Operating Procedure

2 Who should read this document?

Radiologists, Superintendent Radiographer, imaging technicians and the Imaging Research Assistant.

3 Procedure to Follow

The RD&I Office will send a copy of the approved research protocol to the UHPNT Imaging Research Assistant who will distribute the imaging information to the Superintendent Radiographer, Consultant Radiologist and imaging technicians carrying out the imaging for the research project.

The Imaging Research Assistant will maintain a register of approved research studies and when applicable, include details of equipment and set-up parameters for collecting the research images (to ensure consistency in the equipment used e.g. for MRIs the same scanning heads are used). The exposures and dose constraints and will also be

recorded to ensure that the total dose from all exposures associated with the protocol does not exceed the dose constraint or target dose.

The referrer (Study Research team) who signs requests for research exposures will ensure that reference to the research study is included in the clinical details.

Before imaging the Superintendent Radiographer and Consultant Radiologist will check that the equipment is as specified at the study initiation meeting. If changes need to be made to equipment for maintenance reasons then the study CI/PI must be informed and they will notify the study sponsor.

Equipment and Quality Assurance Testing

The Superintendent Radiographer is expected to:

- have detailed knowledge of the equipment in order to ensure that it is appropriately set up for the research study.
- manipulate the equipment correctly so that patient safety is not compromised
- ensure that an agreed quality assurance programme is in place that incorporates the regular inspection of equipment

The stated aim of quality assurance procedures applied to equipment is to ensure consistent and acceptable levels of performance of the imaging system and image recording facilities.

This programme includes a policy on:

- electrical safety tests carried out at least once a year by qualified personnel[1]
- baseline/acceptance testing of all new or upgraded equipment, and following major repair
- user tests including weekly inspection of cables, transducers, monitor and image recording facilities.

The quality assurance programme has been developed in discussion with medical physics and service engineers, for each individual machine. This is based on its clinical uses, the modes and functions utilised. The quality assurance programme indicates clearly the limits of acceptability for each test, what and by whom action should be taken when these are exceeded.

The Superintendent Radiographer responsibilities in relation to the imaging equipment include:

- appropriate selection of the imaging parameters for the research examination
- manipulation of the controls to maximise the clinical information observed

- awareness of system artefacts and how to interpret their appearances
- ensuring that the equipment is suitably maintained to provide optimal images
- ensuring that all equipment is appropriately prepared and cleaned according to the manufacturers' guidelines.
- awareness of and adherence to local infection control procedures
- ensuring that the recorded image is an accurate record of the displayed real-time information
- following the proper shut-down procedure for the equipment, so that stored data and settings are not corrupted or lost
- inspection for electrical and mechanical safety, ensuring that apparently unsafe equipment is not used until it has been checked and repaired
- agreement of equipment performance criteria for each type of research examination undertaken
- reporting any concerns in relation to the performance of specific equipment
- awareness of current guidelines regarding the replacement of equipment

4 Document Ratification Process

The review period for this document is set as ***default of three*** years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be approved by a Trust Senior Consultant Radiologist.

Non-significant amendments to this document may be made, under delegated authority from a Senior Consultant Radiologist, by the nominated author. These must be ratified by a Senior Consultant Radiologist.

Significant reviews and revisions to this document will include a consultation with ***appropriately knowledgeable staff***. For non-significant amendments, informal consultation will be restricted to ***staff*** who are directly affected by the proposed changes.

Dissemination and implementation

4.1. Dissemination of this SOP

4.1.1. New SOPs and new versions of existing SOPs: The Research Governance Manager will be responsible for ensuring authorised SOPs are uploaded on the RD&I intranet site. Internal Trust Staff are expected to use the RD&I intranet site to access latest versions of SOPs and to check the website regularly for updates.

Notice of new or amended procedural documents that have undergone a major amendment will be given *via* the following routes:

• Inclusion in the Trust weekly e-bulletin Vital Signs

• Direct email to Trust Researchers and or teams

4.2. Training in this SOP

4.2.1. All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP.

5 Reference material

1. MHRA "Managing Medical Devices: Guidance for healthcare and social services organisations" April 2015 https://www.gov.uk/government/publications/managing-medical-devices

6 Amendment History

Version Number:	1.1
Date Of Amendment:	Jan 2019
Details Of Amendment:	Updated Trust and Dept. name; Reduce signature requirement to single senior RD&I Manager.