Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Research Department

STANDARD OPERATING PROCEDURE

Use of Radiation in Research

SOP History	*None*
SOP Number	*C113*
Created	*Lance Burn, Research Coordinator*
SUPERSEDED	*v1.0, 08 March 2012*
Version	*2.0*
Date	*19 Nov 13*
Related SOPs	*Not Applicable*
Approved by	*Dipak Patel, Research Manager*

Standard Operating Procedure: Research Department

Use of Radiation in Research

This SOP has been produced in accordance with the following:

- The Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER) as amended by the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006
- The Medicines for Human Use (Clinical Trials) Regulations 2004
- The Medicines (Administration of Radioactive Substances) Regulations 1978 (MARS) as amended by Medicines (Administration or Radioactive Substances) Amendment Regulations 2006
- The Ionising Radiations Regulations 1999

This SOP will outline the procedure for gaining the appropriate permissions at STH to carry out research that involves the use of ionising radiation where:

i) the ionising radiation exposure is the subject of the research
ii) the ionising radiation is associated with diagnostic imaging or forms part of the standard therapy for the participants

Background

The Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER) govern the exposure to ionising radiation of patients or other persons voluntarily participating in medical or biomedical, diagnostic or therapeutic research programmes. Procedures involving ionising radiation include: diagnostic X-rays, CT scans or DXA scans, radiotherapy (including Brachytherapy), therapy using unsealed sources and radionuclide imaging (including diagnostic imaging and in vitro measurements). Magnetic Resonance Imaging (MRI) or ultrasound investigations do **not** involve ionising radiation.

IRMER places responsibilities on:

- The NHS Trust, or other responsible employer at each research site, represented by its Chief Executive
- Researchers requesting examinations involving ionising radiation for the purposes of research
- Practitioners justifying and authorising individual research exposures
- Operators carrying out medical exposures for the purposes of research

IR(ME)R requires that any “research exposure”, even if it is considered standard of care, is reviewed and approved by a Research Ethics Committee (REC).

A REC will review radiation dose and risk assessments performed by the following two experts:

- Medical Physics Expert (MPE) who is a Registered Clinical Scientist registered with the Health and Care Professions Council and has expertise relevant to the planned exposures.
- Clinical Radiation Expert (CRE) who is a registered doctor or dentist with clinical expertise relevant to the planned exposures.

At STH local permissions are sought from the Principle Investigator (PI), an MPE, a CRE and where additionally appropriate a radiographer (operator). The gate keeper sign-off that assures STH that IR(ME)R is complied with is the electronic approval sign-off on Research Management System (RMS) by a competent MPE, email approval by a competent CRE uploaded to the document repository (currently Alfresco) and electronic sign off provided by the MIMP Research Co-ordinators on RMS.

Importantly, this sign-off is not the permission of MIMP in terms of capacity or cost to undertake procedures. MIMP staff may be the competent MPE or CRE at STH to review compliance with IRMER for procedures using ionising radiation that are organised by a different service provider.

Services provided by Non-MIMP providers but which IR(ME)R compliance may involve MIMP Staff include:

- PET Scans (Service provider is Alliance Medical)
- DXA Scans (Service providers are Cancer Clinical Trials Centre, NGH CRF)
- Vascular/Cardio Angiography (CRE are Non-MIMP Staff)

Where research involves the use of a number of different ionising radiation medical exposures then review may need to be undertaken by a number of MPEs and/or CREs. An MPE or CRE may only be qualified to advise on one modality. Where MIMP staff are competent to review all the ionising radiation medical exposures then MIMP will coordinate the review.
However, where radiation is involved that is outside the competencies of MIMP staff (for example therapeutic ionising radiations are involved) then further coordination of sign-off is required by the study or R&D Coordinator.

Definition

This SOP defines the steps that must be taken by a Principal Investigator, Study Coordinator or R&D Coordinator to ensure that IR(ME)R is complied with. The SOP covers all possible ionising radiation medical exposures. The SOP covers the processes for **both** Lead MPE and CRE assessments and Local MPE and CRE assessments. Both Lead and Local Site MPE and CRE assessments incur a cost.

Procedure

1. Lead MPE/CRE Assessment

1.1. Chief Investigator, Study Coordinator or R&D Coordinator describes all ionising radiation exposures that could be performed in the course of a research project on the current version of the MIMP form. The exposures considered standard of care (SOC) and those additional must be identified.
- Even where a research project may result in less ionising radiation exposures, compared to standard of care for a participant, all exposures must be recorded on the MIMP form (if available at this stage) and assessed by a competent MPE and CRE.

1.2. Chief Investigator, Study Coordinator or R&D Coordinator submits the completed MIMP form together with a Protocol and Participant Information Sheet (PIS) to the MIMP Coordinator: (sally.fleming@sth.nhs.uk, bridget.billingham@sth.nhs.uk).

1.3. MIMP Coordinators will inform Chief Investigator, Study Coordinator or R&D Coordinator of any additional information / clarifications required and report that MIMP staff are competent to review all aspects of the radiation exposures proposed in the protocol.

1.4. MIMP Coordinators will inform the applicant if MIMP staff are not competent to review all radiation exposures in a protocol and may provide information on who else in STH may be the competent MPE/CRE.

1.5. MIMP Coordinators will provide a cost letter for MIMP's activity in reviewing the protocol and completing a lead MPE / CRE assessment.

1.6. Chief Investigator, Study Coordinator or R&D Coordinator will confirm to MIMP Coordinators that funding is available to cover MIMP's activity.

1.7. MPE will provide the recommended wording for inclusion in section B of the IRAS application and risk statement in the PIS. The MPE will also comment on suitability of wording of radiation risk in PIS in relation to patient cohort

1.8. The CRE will assess whether any of the exposures listed in the trial protocol are considered to be additional to SOC and inform whether they believe the nature and frequency of imaging is appropriate (i.e. justified) for the trial patients.

1.9. Chief Investigator, Study Coordinator or R&D Coordinator will input details into IRAS form and request electronic authorisation through IRAS from the appropriate MIMP staff identified in the information provided in section 1.7 above. Alternatively, the Lead MPE / CRE may do this.

1.10. The Research Ethics Committee review section B of the IRAS form and the risk statement in the PIS and give their approval that the ionising radiation exposures are ethical.

2. Local Site MPE/CRE Assessment, Cost and Capacity requests for MIMP procedures

2.1. Principal Investigator, Study Coordinator or R&D Coordinator describe all ionising radiation exposures that could be performed in the course of a research project on the current version of the MIMP form. The exposures considered standard of care and those additional at STH must be identified.
- Even where a research project may result in less ionising radiation exposures, compared to standard of care for a participant, all exposures must be recorded on the MIMP form and assessed by a competent MPE and CRE.

2.2. Principal Investigator, Study Coordinator or R&D Coordinator submit the completed MIMP form together with a Protocol, Participant Information Sheet (PIS) and NHS R&D Form to the MIMP Coordinators Sally Fleming and Bridget Billingham. If in the opinion of the CRE the protocol requires a Nuclear Medicine procedure that differs from or is above standard of care at STH the ARSAC application form should be transferred in IRAS to either Sally Fleming or Bridget Billingham (sally.fleming@sth.nhs.uk, bridget.billingham@sth.nhs.uk).

2.3. MIMP Coordinators will inform the applicant if MIMP staff are not competent to review all radiation exposures in a protocol and may provide information on who else in STH may also need to provide an assessment of the ionising radiation that MIMP staff are not competent to review.

2.4. MIMP Coordinators will identify procedures that can be assessed for IR(ME)R compliance by MIMP staff but that are not provided as a service by MIMP (for example: PET, DXA and vascular or cardio radiology).

2.5. MIMP Coordinators will provide the costs for MIMP activity in the research project to the Principal Investigator, Study Coordinator or R&D Coordinator.

2.6. The MPE(s) and CRE will provide an opinion as to whether IRMER compliance can be demonstrated. Additional information may be requested from the PI or the Co-ordinators to facilitate this decision. A summary of this assessment will be recorded on RMS.

2.7. MIMP Co-ordinators will organise the electronic sign off on RMS by the competent MPE/CRE. The appropriate documents confirming approval will be uploaded to Alfresco.

3. Procedure for assessing IR(ME)R Compliance where a protocol requires radiotherapy

Note: Radiotherapy Physics is a totally separate Directorate to MIMP.

3.1. The Head of Radiotherapy Physics (HoRTP) at WPH (Stephen Tozer-Loft) will undertake the role of Medical Physics Expert for the review of radiotherapy dose in clinical trials. An email approval summarising this assessment will be recorded on RMS (normally by R&D Coordinator).

3.2. The Study or R&D Coordinator will provide HoRTP with Protocol, main REC application, local PIS, NHS R&D Form and any other necessary documents.

3.3. For clinical trials involving standard care radiotherapy the local PI may not be a Clinical Oncologist (radiotherapy specialist). Therefore the clinical input into determining that the trial radiotherapy is acceptable will be sought from a clinical oncologist, acting as a Local Practitioner. The HoRTP may be well-placed to identify a suitable Local Practitioner.

3.4. For clinical trials involving comparison of radiotherapy doses the local PI is likely to be a clinical oncologist. Therefore, local PI can act as Local Practitioner.

3.5. The Local Practitioner will advise that STH can adhere to the protocol and either that:
   a. The radiotherapy doses in the protocol (including associated planning and verification images) are normal practice at STH, or
   b. Where local patients would receive a dose different to normal practice at STH, that:
      i. this has been identified in the REC application and has been approved by the main REC, and that
      ii. any ‘additional exposure’ is justified with an acceptable balance for efficacy vs toxicity and having regard to IRMER. (Note that in radiotherapy, a decrease in dose (or ‘exposure’) may have a larger effect on patients if it is accompanied, for instance by a change in the number of fractions or the intervals between them)
      iii. that the risk associated with the change in radiotherapy treatment is adequately described in the PIS

3.6. HoRTP will report on whether STH has the capability to deliver the radiotherapy doses and techniques required by the protocol

3.7. The Local Practitioner will report on whether the contents of the PIS are reasonable.

3.8. For the review of radiation used in diagnosis and testing in research. The procedure described in section titled: Local Site MPE/CRE Assessment, Cost and Capacity requests for MIMP procedures should be followed.

3.9. Determination of the total radiation dose in a trial, because of the clinical condition of the patients involved, does not need to be reported, therefore the separate confirmations of STH NHS FT compliance with IRMER described in 3.6, 3.7 and 3.8 is satisfactory.

3.10. In the temporary absence of HoRTP, the Lead Clinician for Radiotherapy (Dr Simon Pledge) will co-ordinate the response of the Clinical Oncologists (local practitioner) and approach a Principal Physicist (Steven Young) to act as MPE to allow a preliminary decision to be made about capability. This should be forwarded to the HoRTP on their return from absence.

Appendix- Associated Documents

	Document	S-drive	Website	Database	Who
1	MIMP Form	S:\General\Research Governance\Project Authorisation\Templates\RD templates\MIMP Research Approval Form Vers 8.doc	Yes	No	MIMP