Document Control Report

Title Making Ionising Radiation Exposures for the purpose of Research - IR(ME)R 2017 Standard Operating Procedure					
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CONTENTS

1. Introduction

The Ionising Radiation (Medical Exposure) Regulations {IR(ME)R} 2017 were introduced to protect patients against the hazards associated with the use of ionising radiation in medical settings. Where ionising radiation is used for research purposes clear pathways and protocols must be followed to ensure adherence to IR(ME)R guidelines but also dose reference levels for examinations are kept to the minimum required to ensure patient safety.

All research procedures involving ionisation radiation require specific Research Ethics Committee approval in advance of the study commencement. These exposures to ionising radiation are described within the IRAS ethics form, including details of expected exposures and justification for those exposures.

As part of the Trust Research Ethics Committee (REC) approval process for research projects, the Practitioner (Radiologist) provides generic justification for exposures identified in that research proposal. Only where the REC has referred the proposal to the Practitioner for approval, will the Practitioner carry out justification.

2. Purpose

The Standard Operating Procedure (SOP) has been written to:

- Clarify the process involved in obtaining authorisation for making medical exposures for research purposes.
- Identify the roles and responsibilities of those involved in obtaining authorisation for radiation exposures for research purposes.
- Identify the roles and responsibilities of those involved in making the radiation exposures for research purposes.
- Keep dose reference levels of research radiation exposures as low as is reasonably applicable (ALARA), particularly for those that have no direct benefit to the health of participants.

3. Scope

This Standard Operating Procedure (SOP) relates to the following staff groups who may be involved in the making of or requesting ionising radiation exposures for research purposes:

- Radiographers (Operators)
- Radiologists (Practitioners)
- Research Nurses
- Medical Staff
- Allied Health Professionals

- Medical Physics

4. Location

This Standard Operating Procedure applies to Researchers and Practitioners carrying out research in the Northern Devon Healthcare Trust.

Staff undertaking ionising radiation exposures for the purpose of research must be able to demonstrate competence as per the organisations policy on assessing and maintaining competence.

5. Equipment

- Ethics approval letter.
- Research & Development (R&D) form & Research Ethics Committee (REC) application.
- Study Protocol & Patient Information Sheet.
- Radiology imaging equipment
- Radiology consent form

6. Procedure

The R&D department will email Radiology for Local Practitioner IRMER assessment and authorisation as early as possible in the approval process.

The Local Practitioner will assess the following:

- Review the protocol and R&D form and confirm that the site/radiology department can adhere to the protocol
- Has the additional exposure been identified in the R&D form and been ethically approved?
- Any additional exposure is justified, taking into account:
- - Diagnostic or therapeutic benefits to the individual and society
- - Objectives of exposure
- - The detriment that the exposure may cause
- - The availability of alternative techniques involving less or no radiation
- - The possibility that participants will be participating in other trials involving additional radiation – See questions A17 & A32 of Rec application
- The practitioner is required by IRMER to pay special attention to research exposures that have no direct health benefit for participants. In the rare cases where there is no benefit to the individual the setting of a dose constraint is required.

- In cases where the person undergoing the examination benefits from the exposure, the practitioner is required to plan individual target levels of dose. These are set at the time of justification and take into account the age of the individual and any other factors which affect the risk of that examination.

- In the rare cases where there is no benefit to the individual, the setting of a dose constraint is required. This is determined from the level of benefit to society, as detailed below:

Required benefit to Society	Dose Constraint (mSv)	Risk	Level of risk
Minor	0.1	1×10^{-5}	Trivial
Intermediate	0.5	5×10^{-5}	Minor
Moderate	5	5×10^{-4}	Intermediate
Substantial	10	1×10^{-3}	Moderate

Definitions of Benefit

Minor: expected only to increase knowledge.
Intermediate: related to increases in knowledge leading to health benefit.
Moderate: aimed directly at the diagnosis, cure or prevention of disease.
Substantial: directly related to the saving of a life or the prevention or mitigation of serious disease.

- These constraints are for **adults under 50 years**. The values are increased by a factor of 5 for those over 50 and reduced by a factor of 3 for children.

- Patients concerned must participate voluntarily and pass through a formal consent process including discussion of ionising radiation risks; Patients concerned must be informed of the risks of the exposure.

The Medical Physics Expert (MPE) will assess the following:

- The exposure can be performed at the site within the estimated range of dose made by the lead medical physics expert.

- Local dose per examination will not exceed the maximum exposure estimated in the REC application.

- Approved Patient information sheet accurately reflects the additional radiation and risk to which local participants will be exposed

The MPE will set dose constraint and / or target dose for IRMER purposes.

7. References

- Ionising Radiation (Medical Exposures) Regulations 2017. Statutory Instruments 2017 No 1322
  http://www.legislation.gov.uk/uksi/2017/1322/pdfs/uksi_20171322_en.pdf

- Radiology authorisation and IRMER assessment working practice document.

- Ionising (Medical Exposures) Regulations 2000. Statutory Instruments 2000 No 1059 –

http://www.opsi.gov.uk/si/si2000/20001059.htm

- IRMER – Ionising Radiation (Medical Exposures) Amendment Regulations 2006

http://www.opsi.gov.uk/si/si2006/uksi_20062523_en.pdf

8. Associated Documentation

Northern Devon Healthcare NHS Trust Policies for:

- Northern Devon Healthcare NHS Trust Radiation Policy
- Northern Devon Healthcare SOP ‘Making a Referral for Diagnostic Imaging’

For further information please see: National Research Ethics Service (NRES) Approval for research involving ionising radiation Version 2 September 2008

http://www.hra.nhs.uk/documents/2013/09/approval-of-research-involving-ionising-radiation-september-2008.pdf

9. Appendix A Radiology Authorisation and IRMER Assessment

Radiology authorisation and IRMER assessment working practice document

Local practitioner and RM&G process

RM&G staff emails Radiology for Local Practitioner IRMER assessment and radiology authorisation as early as possible in the approval process

Contact: Jenny MacPherson jennifer.macpherson@nhs.net

See email template for email content (Appendix A) and study break down

Attach the following documents for review

-Ethics approval letter

-R&D form & REC application

-Protocol

Local practitioner to issue assessment to R&D) within 14 days

R&D forward study documents to the Medical Physics Expert in Exeter for review and authorisation. Study documents to send to medical physics expert

-Ethics approval letter

-R&D form & REC application

-Protocol & patient information sheet

Contact: tbc

Local practitioner to assess the following

- Review the protocol and R&D form and confirm that the site can adhere to the protocol
- Has the additional exposure been identified in the R&D form and been ethically approved
- Any additional exposure is justified, taking into account
  -diagnostic or therapeutic benefits to individual and society
  - Objectives of exposure
  - The detriment that the exposure may cause
  - The availability of alternative techniques involving less or no radiation
  - The possibility that participants will be participating in other trials involving additional radiation – See questions A17 & A32 of Rec application
- The practitioner is required by IRMER to pay special attention to research exposures that have no direct health benefit for participants

Medical Physics Expert to assess the following

- Protocol can be performed at the site within the estimated range of dose made by the lead medical physics expert
- Local dose per examination will not exceed the maximum exposure estimated in the REC application
- Approved Patient information sheet accurately reflects the additional radiation and risk to which local participants will be exposed
- Set dose constraint and / or target dose for IRMER purposes

Radiology will be approached by the leading Research nurse at the feasibility stage for initial assessment of capacity and the trusts ability to adhere to the study. This approach will be documented on the research and development departments feasibility form.

The R&D administrators will follow up this with the IRMER assessment and Radiology authorisation email once feasibility has been established and the trust are able to successfully run the study.

Local practitioner document review – helpful information

The relevant information for the local practitioner assessment can be found within the protocol and the following sections of the R&D form

Section B – Ionising radiation

Section C – Dose and Risk

Section D- Clinical Assessment

The ethics approval is given on the content of the REC / R&D form application.

Protocols vary in content; the R&D email will contain the page numbers of the protocol relevant to radiology.

Medical Physics Expert

The Medical Physics experts are based in Exeter and will process the IRMER assessment for the study at North Devon District Hospital. This is in line with the trust policy and service level agreement between the services.

10. Appendix B Email to local practitioner

Email Template to Local practitioner

Contact:

Dear

Please see the attached documentation for the ….. Study. In order to proceed with issuing NHS permission, we require local practitioner assessment for IRMER and an authorisation for radiology's capacity to adhere to the attached protocol.

The study recruitment target is

With a recruitment window, of

The number of x-rays/CT/MRI scans per patient is … over … of years

The relevant pages in the protocol are …. For your review.

These scans have been costed for and the radiology department will be reimbursed £… for each patient consented to take part in the study.

Can you please assess the attached study documentation and confirm your authorisation to the research and development department via email with by *insert date……...*

If you require any further documents or additional information, please let us know.

Many thanks

11. Appendix C Email to Medical Physics

Email template to Medical Physics expert

Contact:

Dear

Please see the attached documentation for the ….. Study. In order to proceed with issuing NHS permission, we require Medical physics expert assessment for IRMER. Can you please assess the attached study documentation and confirm your authorisation to the research and development department via email?

If you require any further documents or additional information, please let us know.

Many thanks