GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol
Cwm Taf Morgannwg
University Health Board

EP7 Schedule 2, 1 (g) Procedure for exposures carried out as part of biomedical and medical research programmes

Initiated by:	Radiology
Authors:	Alex Wallace, Sarah Rees, Ian Mcilquham
Approved by:	Radiation Safety Committee
Date approved:	April 2025
Version:	3.0
Operational date:	April 2025
Date for review:	March 2027
Distribution:	Radiology, SharePoint
Audit required:	Yes, compliance with procedure

Procedure
A procedure is a set of detailed step-by-step instructions that describe the appropriate method for carrying out tasks or activities to achieve a stated outcome to the highest standards possible and to ensure efficiency, consistency and safety.

Amendment Record
If a change is required to the document, please identify the change below and update the version number.

Type of change	Why change made	Page number	Date of change	Version Number	Name of responsible person
Whole document Creation	First issued as new document to include: • overview of legal requirements • reference to new ABMU policy on implementation of IR(ME)R list IR(ME)R employer's procedures		Oct 18	1.0	J. Roberts
Minor amendments following comments	Change of Logo from ABMU to Cwm Taf		Apr 19	1.1	I. Mcilquham
	Removed requirement for Radiology Manager to sign a review box.		Jun 22	2.0	I. Mcilquham
	Addition of Hyper-links		Nov 22	2.1	I. Mcilquham

Whole document review	Procedure to include all CTM sites Change of author due to change of roles in radiology		March 2025	3.0	Sarah Rees

Contents

Amendment Record 2
Purpose 5
Scope 5
Responsibility 5
Documents 5
Procedure 5
References 8

Purpose

To ensure that all research studies requiring medical radiation exposures in Radiology restrict any dose of ionising radiation to the minimum required to achieve the intended clinical objective and comply with IR(ME)R and associated guidance.

All required research assurances must be acquired (e.g. Health Research Authority, HRA) and research ethics committee (REC) approvals, local feasibility and local R&D approvals have been obtained.

Scope

Medical radiation exposures in diagnostic radiology and nuclear medicine required as part of approved research studies.

Responsibility

Liaison between the Principal Investigator (PI), R&D Department, Site Lead Radiographer/Technologist (or Research Radiographer if applicable), IR(ME)R Practitioner and Medical Physics Expert (MPE) is required to achieve IR(ME)R compliance. (See **Appendix 1** for further description of roles).

Documents

- IRAS form (also known as R&D or REC form)
- Study Protocol
- Participant Information Sheet (PIS)
- Research Exposure Authorisation Guideline form
- MPE Radiation Governance Review form

Procedure

1. Following identification of and liaison with the PI, the R&D department will email each applicable Lead Radiographer (or Research Radiographer) to request they initiate Local IR(ME)R Practitioner review and appropriate MPE assessment. No initial trials are started within the health board.

2. ***Local IR(ME)R Practitioner will:***

   2.1 Review the approved research protocol and IRAS form and confirm that the radiology/nuclear medicine department can adhere to the protocol.

   2.2 Confirm that any exposures in addition to local standard of care have been identified in the IRAS form and been ethically approved.

   2.3 Confirm that any additional exposure is justified, taking into account:

   - Diagnostic or therapeutic benefits to the individual and society
   - Specific 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 IRAS form

2.4 The practitioner must pay special attention to research exposures that have no direct health benefit for participants.

2.5 Justification will be granted by the practitioner prior to commencement of each study by completing a "***Research Exposure Authorisation Guideline***". This document will clearly outline the criteria to be met locally by study participants presenting for imaging in order to enable authorisation of individual exposures by entitled operators. The document will also clearly detail the exposures to be performed locally in order to satisfy the research protocol.

2.6 The completed *Research Exposure Authorisation Guideline* will be returned via email to the PI and R&D department identifying any outstanding issues or confirming justification of the exposures. The Lead site radiographer/technologist (or research radiographer) and Local MPE will be copied in.

2.7 Studies involving several exposure modalities/specialties e.g. nuclear medicine plus diagnostic radiology, will likely require involvement of multiple Practitioners to cover each discrete modality for which they are entitled to act as Practitioner. The above assessment will be completed by each Practitioner. Collaboration between the Practitioners will allow a single *Research Exposure Authorisation Guideline* to be completed and returned.

3. ***Local Medical Physics Expert (MPE) will:***

3.1 Confirm that all exposures taken together can be performed at the proposed site/department within the estimated total research protocol dose (TRPD) set by the Lead MPE in the IRAS form.

3.2 Confirm that the local dose per examination will not exceed the maximum exposure for each examination estimated by the Lead MPE.

3.3 Confirm that the approved patient/participant information sheet (PIS) provided to the patient in advance accurately reflects and appropriately communicates the additional radiation and associated risk to which local participants will be exposed.

3.4 The MPE will set clear local dose constraints (where there is no direct medical benefit) as applicable using relevant dose metrics to ensure local optimisation of the exposures.

3.5 For studies involving administration of radioactive substances to patients/participants the MPE in Nuclear Medicine will also advise on the licensing requirements for the Health Board and Practitioner.

3.6 The outcome of the MPE assessment (addressing 3.1 to 3.5 above) will be recorded in an "***MPE Radiation Governance Review***" form which will be returned via email to the PI and R&D department identifying any outstanding issues or confirming approval. The Lead site radiographer/technologist (or research radiographer) and IR(ME)R Practitioner will be copied in.

3.7 Studies involving several exposure modalities e.g. nuclear medicine plus diagnostic radiology will require collaborative involvement of multiple MPE's to cover each discrete modality for which they are registered and entitled. The above assessment will be completed by each MPE for their own areas of expertise. Collaboration between the MPE's will allow a single Local *MPE Radiation Governance Review* form to be completed and returned.

4. ***The Lead Site Radiographer (or Research Radiographer) will:***

4.1 Following receipt of documentation from the IR(ME)R Practitioner and local MPE clearly stating the exposures approved to be performed locally, seek confirmation from the R&D Department and PI of when the study can commence.

4.2 Liaise with the manager of the service carrying out the exposures (e.g. Radiology Services Manager) to discuss and agree which and how many exposures will be performed as part of the study.

4.3 Add the study details to the local ***research register*** of all ongoing approved research studies within the department. The register will contain details of the authorised exposures and as a minimum contain;

- The number and type of required exposures, including protocol details (indicate "routine protocol" if applicable)
- Authorisation Guideline and MPE Governance Review
- The set dose constraints for each examination
- Contact details for members of the research team and expected end date

4.4 Review and audit entries of delivered doses to patients/participants made in the research register by entitled radiographers to ensure that they are complete and in compliance with set dose constraints where applicable.

5. ***All Radiographers/ Clinical Technologists entitled to expose study participants will:***

5.1 Confirm that all referrals for exposure of patients/participants involved in an approved study are clearly indicated (including the study name) on the request form. Referrals where the study name is not indicated will be returned.

5.2 Refer to the research register to determine and confirm the required exposure details for the identified study.

5.3 Confirm the following with the patient prior to exposure;

- They are aware that the exposure is being performed as part of the study and are participating voluntarily
- They have consented to take part in the study and have read the PIS explaining the radiation risks

5.4 In addition to the requirements of the Employers Procedure on Patient Dose Assessment & Recording the radiographer will record the dose delivered to the patient/participant for each examination (including the exposure indicator units) in the research register under the relevant study heading. This will enable compliance with the set dose constraint to be audited by the Lead radiographer/technologist. Where set dose constraints or target doses have been exceeded the reason must be clearly documented.

5.5 Ensure that pregnant women and children are not exposed as study patients/participants. Adults who lack the capacity to consent must be excluded as study patients/participants.

References

Department of Health. *The Ionising Radiation (Medical Exposure) Regulations 2017*. London: The Stationery Office, 2017.

Guidance to the Ionising Radiation (Medical Exposure) Regulations 2017 (publishing.service.gov.uk)

NHS Health Research Authority Radiation Assurance, 2018. https://www.hra.nhs.uk/about-us/committees-and-services/technical-assurances/radiation-assurance/applying-radiation-assurance/

Approval for research involving Ionising radiation, v2.0 (2008). http://www.hra.nhs.uk/documents/2013/10/approval-of-research-involving-ionising-radiation-2.pdf.

Appendix 1 Overview of Roles

All approved research studies/trials involving radiation exposures must involve the following personnel to ensure IR(ME)R compliance at a participating site;

- ***Principal Investigator (PI)***

  The lead investigator responsible for the conduct of the research at each site (if multi-site project) and for applying to the local R&D office.

  The PI will usually be the same person as the CI for the lead site.

- ***Local Medical Physics Expert (MPE)***

  The Local MPE should be a registered healthcare professional (e.g. with Health and Care Professions Council, HCPC) and formally recognised as an MPE in the UK under IR(ME)R 2017 with expertise relevant to the modality involved in the study.

  The Local MPE should also understand the characteristics of the research population in order to review and approve the dose and risk assessment completed by the lead MPE. It may be necessary for several modality specific MPEs to be involved in a single study with a nominated "Reviewing MPE" responsible for coordinating a joint review.

- ***IR(ME)R Practitioner***

  All exposures must be justified locally by an entitled IR(ME)R *practitioner*. For lead site studies this role is expected to be fulfilled by the same individual as undertakes the Clinical Radiation Expert (CRE) role.

  The *practitioner* should be a registered healthcare professional (e.g. with HCPC) with clinical expertise in the modality involved in the study (typically a radiologist, clinical oncologist or nuclear medicine specialist).

- ***Lead Radiographer/Technologist (or Research Radiographer)***

  Responsible for ensuring that the practical requirements of this procedure are met locally within their department prior to and throughout the study for all patients/participants.

- ***Entitled Radiographers***

  IR(ME)R Operators entitled to perform the practical aspects of exposures on research patients/participants.

Appendix 2 Glossary

ARSAC	Administration of Radioactive Substances Advisory Committee. ARSAC certificates are required by clinicians wishing to administer radioactive medicinal products to humans.
CI	Chief Investigator
CRE	Clinical Radiation Expert
HRA	Health Research Authority
IRAS	Integrated Research Application System
Modality	Imaging/treatment method
MPE	Medical Physics Expert
NRES	National Research Ethics Service
PI	Principal Investigator
PIS	Participant Information Sheet
R&D	Research & Development
REC	Research Ethics Committee
SSI Form	Site-Specific Information Form (available in IRAS)
TRPD	Total Research Protocol Dose