Title of Document:	**IR(ME)R Procedure (G)** to identify responsibilities and the essential considerations when carrying out a radiation exposure as part of a research programme
Directorate:	RADIOLOGY DIRECTORATE

Document type & number:	IRMER 7
Approval committee:	DIRECTORATE AND GOVERNANCE GROUP
Approval date:	14.05.2025
Issue date following approval/review/ amendment :	20.05.2025
Review date:	14.05.2028
Version number:	V3
Key amendments:	Date:
Minor rewording to ensure compliance with IR(ME)R (Amended) 2024 update Inserted references to the participant's representative as per Reg 12(4)	
Individuals involved in developing / reviewing / amending this document: (titles only)	
RPS	11.02.2025
RPA	March 2025
Radiation Protection Committee	24.03.2025
Key staff responsibilities	Post:
Responsible for ensuring that research proposals submission include adequate information and identify responsibilities	Local research ethical committee
	ARSAC
Responsible for giving a clear indication on the request form that the exposure is required for this reason.	The referrer

In-line with regulation 6 schedule 2 (g) requirements within IRMER 2017, the purpose of this procedure is to identify responsibilities and the essential considerations when carrying out a radiation exposure as part of a research programme.

It will determine that the matters set out in regulation 12(4) are established by the employer for biomedical and medical research programmes falling within regulation 3(c) where no direct medical benefit for the individual is expected from the exposure.

This procedure should be used in conjunction to the **Research Governance Policy**

- http://whitsweb/KeyDocs/KeyDocs/DownloadFile/2906

This procedure applies to all persons exposed to radiation as part of a medical or biomedical research programme. This includes the following types of volunteers:

- patients who may benefit from the research
- patients who agree to take part in procedures which will not benefit themselves directly
- healthy volunteers
- All volunteers (or their representative) must consent to take part and be screened to ensure suitability.

All volunteers must be screened to ensure suitability.

Definition:

The Health Research Authority defines exposures to ionising radiation as 'research exposures' where both the following criteria are met:

a. The exposure is required as an integral part of, and for the purpose of, the research.

b. Consent for the exposure is sought from the potential participant as a part of their consent to take part in the research (including screening for eligibility).

https://www.rcr.ac.uk/system/files/publication/field_publication_files/irmer-implications-for-clinical-practice-in-diagnostic-imaging-interventional-radiology-and-nuclear-medicine.pdf
(pages 104- 108)

Practice:

NO CURRENT

Approval:

All research programmes must have approval from the National/Local Research Ethics Committee (N/LREC) before commencing. (This applies even if they have been submitted to a multi-centre research ethics committee).

All research programmes involving the administration of radioactive substances to persons must comply with section 4 of the ARSAC notes for Guidance March 2018. "Applying for Research Authorisation"

Submissions involving radiation exposures should:

1. Include the volunteer consent form
2. Include the proposed benefits and radiation risks from the study to the volunteer:
   - The risks associated with the exposure should be established after consultation between the Practitioner, the relevant Radiation Protection Adviser and Medical Physics Expert. It is the responsibility of the research coordinators to ensure that confirmation of these checks is documented on the request.

3. Include details on the recruitment of subjects for the study
4. Information on dose constraints (see associated research protocol)

   https://www.rcr.ac.uk/system/files/publication/field_publication_files/irmer-implications-for-clinical-practice-in-diagnostic-imaging-interventional-radiology-and-nuclear-medicine.pdf

   - Dose constraints must be set in the planning of any research study from which the participating individual is not expected to receive a direct medical benefit. Such dose constraints and targets should be set after consultation between the Practitioner and Medical Physics Expert. The MPE will provided a report outlining a dose constraint for each examination. This will be based on local dose data where available or national dose data.
   - In the event a dose constraint is exceeded an incident report should be completed on Datix. The Medical Physics Expert should be notified to assess the excess dose to the individual and to recommend whether this incident is reportable to the regulators.

5. Identify who will be responsible for ensuring that:
   a) Subjects participate voluntarily and are informed in advance about the risks of exposure
   b) Dose constraints are adhered to (for individuals gaining no medical benefit)
   - Completed through periodic audit
   c) Individual target doses are planned (for individuals expected to receive medical benefit)
   - For multi Centre trials where the Trust is not the lead site, the local MPE needs to review the Lead MPE's dose and risk assessment to check that exposures locally are within a reasonable margin of the dose constraint
6. Identify the practitioner

Imaging Requests:

- Requests must be easily identified for research. This is done by using specific research related RIS codes and documentation of the specific study code in the clinical history.
- This can then be referenced against the list of current trials available to the radiology staff on Team Share Point (to be created at time of trial).

Post processing:

- As for standard medical radiation exposures, there should be a record of the exposure factors or administered activity (see Procedure E for assessment of patient dose), to enable an estimate of the effective dose to the individual and to ensure compliance with the dose constraint.

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