Worcestershire Acute Hospitals NHS Trust

Breast Imaging Department

Ionising Radiation (Medical Exposure) Regulations 2017
Regulation 6 Schedule 2 Employer's Procedures

(g) Procedure for conducting medical research	
Responsibilities relating to IR(ME)R procedures:	
Ensuring the required IR(ME)R procedures are in place	Worcestershire Acute Hospitals NHS Trust (WAHT)
Authorisation of Breast Imaging IR(ME)R procedures	Clinical Director of Breast Imaging
Development, review and amendment to this document	Superintendent Radiographer
Assisting in development, review and amendment to this document	Radiation Protection Supervisors
Governance pathway:	
Medical Physics Expert review (IRS)	12.7.2024
Submission to Breast Directorate for approval	11.1.2023
Circulation to Women and Children Division for information	1.3.2023
Circulation to Radiation Protection Committee for information	28.4.2023
Authorised by Clinical Director of Breast Imaging	1.3.2023

Version No	Reviewed	Action	Next Review Date
1	9.12.22 IRS	Revision of format and IRMER audit	1.3.2026
2	12.7.2024 IRS JB	No changes	12.7.2025

Purpose

To identify considerations when carrying out a radiation exposure as part of a research programme, determining whether the practitioner or operator is required to effect one or more of the matters set out in regulation 12(4) including criteria on how to effect those matters and in particular procedures for the use of dose constraints 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.

Scope

Applies to all persons exposed to radiation as part of a medical or biomedical research programme.

Responsibility

It is the responsibility of the practitioner to ensure compliance with this procedure.

Procedure

1. The individuals concerned participate voluntarily in the research programme and are informed about the risks of the exposure.
2. All research programmes must be submitted to the Local Research Ethics Committee (LREC) for approval before commencing, whether or not it has been submitted also to a Multi-centre Research Ethics Committee (MREC).
3. Where a research study has received MREC approval, the local MPE must be consulted to review the dose and risk assessment procedure produced by the lead MPE for the study and to advise on whether the dose constraints or target doses can be met at the local site. Such consultation will normally be via the Trust research and development department but may be directly with the mammography department.
4. Approval of the research by the LREC will be dependent on satisfactory demonstration of point 1 (above)