1. Objective

To ensure that all clinical research trials undertaken restrict any dose of ionising radiation to the minimum required to achieve the intended clinical result and that all comply with regulatory requirements.

2. Responsibilities

Responsibilities are clearly explained on HRA Website, & HRA provide an e-learning module.

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/ionising-radiation/

https://www.hra.nhs.uk/planning-and-improving-research/learning/e-learning/

The Chief Investigator has overall responsibility for the conduct of the research and in a multi-centre study will co-ordinate the research from all sites. The Principal Investigator is responsible for conduct of research at a particular site.

The Chief/Principal Investigator is responsible for completing an IRAS form, ensuring that appropriate Clinical Radiation Experts (CREs) (IRMER Practitioners) and Medical Physics Experts are identified and consulted, informing the Research and Development Office of the research to be undertaken, and ensuring that patients are appropriately identified.

The CRE (IRMER Practitioner) determines that there is sufficient net benefit to allow research exposures to go ahead, and ensure that every request is authorised and a clinical evaluation performed.

The Medical Physics Expert performs a dose and risk assessment, and identifies the dose constraint or target dose as appropriate (see definitions in EP(i)).

The Chief Investigator is responsible for ensuring that informed consent is obtained from all potential participants.

The Operators performing practical aspects of the exposure comply with local IR(ME)R procedures for research.

In nuclear medicine the operator performing practical aspects of the exposure must ensure that there is a valid research ARSAC certificate in place.

3. Research involving radiation exposure

All research studies involving patients or volunteers, carried out within the National Health Service, must be approved by the National Research Ethics Service (NRES).
https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/research-ethics-service/
To apply for approval of a research study follow the procedures detailed at:
http://www.nhsresearchscotland.org.uk/services/research-ethics

For studies that involve the exposure of patients or volunteers to radiation, the IRAS application form asks for detailed information on the procedures, patient doses and personnel involved. There are a number of duty holders who are responsible for supplying this information and for ensuring the conduct of the study. For further guidance on the roles and responsibilities of the key individuals within this process refer to the document “Approval for research involving ionising radiation” available at:

https://www.myresearchproject.org.uk/Help/Contents/IRAS%20QSG%20Part%20B%20Section%203%20(version%20dated%20January%2008).pdf

Adherence to the guidance in that document will ensure that the procedures developed comply with IRMER requirements.

4. Patient consent

All potential participants must receive a written explanation of the research programme and its risks and have the opportunity to discuss these with a responsible person before agreeing to take part. The explanation must make clear that treatment will not be prejudiced by failure to take part.

All individuals taking part in a research programme do so voluntarily. Each participant will sign a statement indicating that the whole procedure has been properly explained, that they voluntarily undertake the procedure and are aware of the risks.