1. The application

The Chief/Principal Investigator for each research project is responsible for completing an IRAS form.

The Chief/Principal Investigator must ensure that all potential referrers have a combination of qualifications and training defined in EP2, have been entitled by the IRMER Policy Lead and are aware of requirement in the study protocol.

The Chief/Principal Investigator informs the Research and Development Office of the research and obtains management permission for the research to be undertaken.

The Chief/Principal Investigator ensures that appropriate CREs (IRMER Practitioners) are identified and consulted regarding all medical radiation exposures whether routine or trial specific. At least one CRE is identified for each site for each Research Study involving radiation.

The CRE must have the combination of qualifications and training defined in EP2.

The CRE must determine that there is sufficient net benefit to allow research exposures to go ahead. In arriving at that decision, he/she is required to consider:

- The specific objectives of the exposure and the characteristics of the individual
- The potential diagnostic or therapeutic benefits, including direct benefits to the individual and the benefits to society
- The individual detriment that the exposure may cause
- The availability of alternative techniques involving less, or no, exposure to ionising radiation
- The possibility that participants will be participating in other trials involving additional radiation

The trial sponsor must obtain, and disseminate to the IRMER license holder and to the local site lead, ARSAC research approval for all research projects involving administration of radiopharmaceuticals which result in radiation exposure to individuals additional to that involved in the patient's routine diagnostic management from administration of radiopharmaceuticals. Both the site and the practitioner must hold a research IRMER license for the administration of radioactive substances for the radiopharmaceutical procedure involved in the trial, however specific licenses are not required unless the procedure is not already included on the site and practitioner license.

The Medical Physics Expert (MPE) must perform a dose and risk assessment, and identify the dose constraint or target dose as appropriate (see definitions in EP(i)). All Clinical trials must aim to restrict the dose of ionising radiation to be the minimum requirement to achieve the intended clinical result. The Chief/Principal Investigator should allow at least ten working days for the MPE to carry out the dose and risk assessment.

Approval for a Clinical Trial must be obtained by the Chief or Principal Investigator through submission of a completed IRAS application form to NHS REC.

The application must be approved by an MREC and LREC where appropriate.

2. The study

The Chief/Principal Investigator must ensure that systems are in place to inform any operators, who might be involved in an exposure relating to their study, are made aware that patients are part of a research study when they are referred for imaging. Failure to do so will result in the request being rejected.

It is the responsibility of the individual practitioner for a research study to ensure that every request is justified, but an operator, so entitled, may authorise the exposure, using Practitioner's guidelines. The Practitioner shall ensure that operators are aware that a request is part of a research study.

- Operators must follow any procedure specifically developed for the research study or, where this is not available, the department's procedure for the particular type of examination.
- Operators must report to their line manager any instances where exposures are being made for research purposes where this has not been clearly indicated on the request or if they suspect that the study has not been approved.
- The clinical evaluation must be performed by an appropriately entitled operator, and reported through appropriate communication arrangements.

The end of a Clinical Trial must be identified and its outcome documented.

3. Amendments

The Chief Investigator must ensure that any amendments to the study protocol are notified to the Research and Development office, the LREC / MREC and, where the amendment involves the administration of radioactive substances, the ARSAC.

4. Glossary of Abbreviations

CRE	Clinical Radiation Expert
IRAS	Integrated Research Application System
IR(ME)R	Ionising Radiation (Medical Exposure) Regulations
LREC	Local Research Ethics Committee
MREC	Multi-Centre Research Ethics Committee
NHS REC	National Health Service Research Ethics Committee
NRES	National Research Ethics Service