York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
Standard Operating Procedure
R&D/S64

Research Studies Involving Imaging (studies using ionising radiation & radioactive medicinal products).

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

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Approved by:	Name/Position:	Lydia Harris, Head of R&D
	Signature:	Signed copy held by R&D Unit
	Date:	9th July 2019
	Name/Position:	Sarah Sheath, SOP Controller
	Signature:	Signed copy held by R&D Unit
	Date:	9th July 2019

This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	15th November 2010	
2.0	30th April 2012	Change of SOP Controller. Removal of North and East Yorkshire R&D Alliance references
3.0	6th August 2019	New procedures outlined due to changes in legislation (IRMER 2017) and changes to R&D Unit structure – appointment of Research Delivery Facilitators. Change of link to R&D website.

Contents

1 Introduction, Background and Purpose

Research studies conducted at York and Scarborough Teaching Hospitals NHS Foundation Trust may require support from the Radiology Directorate where imaging for diagnostic or therapeutic purposes is required by a study protocol.

Imaging exposure/ or medical exposure is defined as any exposure to radiation during medical diagnosis or treatment. It can be for routine clinical care or for research. Radiation from medical exposure is categorised as **ionising** (potentially harmful especially in large doses) or **non- ionising** (normally harmless, but harmful in large doses) depending on the energy frequency of the related particles. Medical exposure involves many different types of ionising and non-ionising radiation.

Please note:
Always make sure to check if a procedure involves ionising radiation and radioactive medicinal products to ensure compliance with applicable legislations (see section 1.1).

Examples of procedures involving ionising radiation:

- *Diagnostic radiography (X-rays, CT scans, DEXA scans, Fluoroscopy, CT Angiograms).*
- *Internal radiotherapy (Brachytherapy, Therapy using unsealed sources).*
- *Nuclear Medicine diagnosis (MUGA scans, PET imaging, In-vitro measurements).*

Some procedures which use ionising radiations also utilise radioactive medicinal products (RMPs). These procedures are known as Nuclear Medicine. These procedures raise specific considerations as specified below in the *Applicable legislation* section 1.1.

Types of Nuclear Medicine procedures and common examples:

- *Diagnostic imaging procedures (MUGA multi gated cardiac scans, MPS myocardial perfusion scans, DMSA renal static scans, MAG3 or DTPA renal dynamic scans, SLN sentinel lymph node scan, Iodine whole body scans, Bone and lung scans).*
- *Diagnostic non-imaging procedures (GFR- glomerular filtration rate measurement, red cell mass and plasma volume measurements, B12 absorption measurement, thyroid uptake measurement).*
- *Therapeutic (treatments for a range of cancers, treatments for overactive thyroid).*
- *External radiotherapy (teletherapy).*

Examples of non-ionising radiation procedures:

- *MRI*
- *Ultrasound*

1.1 Applicable Legislation

The following legislation applies to **research projects involving the use of ionising radiation:**

- The Ionising Radiation (Medical Exposure) Regulations 2017 (IRMER) which, together with review by appropriate ethics committees, ensure that the exposures are justified and authorised. **All studies involving ionising radiation must comply with IRMER.**

- Studies involving exposure to radioactive materials **(nuclear medicine) beyond the normal requirements of clinical care require Employer's & Practitioner's IRMER licenses issued by the** Administration of Radioactive Substances Advisory Committee (ARSAC)**.** IRMER states that a person must not administer a radioactive substance in the course of a research programme unless it has been approved by the ARSAC expert committee. All research-indicated nuclear medicine procedures must be included within the scope of the Employer & Practitioner's ARSAC licences. The new Employer and Practitioner ARSAC licences for research are not trial specific (as from February 2018). IRMER 2017 replaced IRMER 2000 (including amendments made in 2006 and 2011). The full regulations can be found on legislation.gov.uk.

  The Ionising Radiation (Medical Exposure) Regulations 2017
  The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2018

  IRMER 2017 changed the process for the administration of radioactive substances with a new licensing system for Employers and Practitioners (the new regulations replaced the certification process for the administration of radioactive substances under Medicines Administration Radioactive Substances 1978 (MARS), and lead to changes in the way ARSAC handles applications). See section 4.4 for more details.

- **CTIMP studies** (Clinical Trials on Investigational Medicinal Product) **involving ionising radiation** must also additionally comply with The Medicines for Human Use (Clinical Trials) Regulations 2004 ("Clinical Trials Regulations").

The purpose of the above legislation is to:

- Protect individuals form unintended, excessive or incorrect medical exposures;
- Ensure individuals receive no more than the required exposure for the desired benefit;
- Ensure that the benefits of exposure outweigh the risks in all cases.

The research provisions of IRMER apply to ANY research exposure involving ionising radiation, not only to exposures that are additional to routine care.

A 'research exposure' is any exposure required by the research protocol following initial consent from the participant. It includes all exposures carried out on the participant as determined by the protocol, including those which would otherwise be part of routine clinical care for patients treated outside the research setting. Research exposures also include any exposure required by the screening procedures for the research. For example, where the protocol requires a diagnostic X-ray to confirm suitability for inclusion in the study, this would be a research exposure that must meet the requirements of IRMER and for which a study participant must provide informed consent. For example, in a comparative study of two radiotherapy schedules (conventional versus ultrafractionated), the control group might be receiving normal radiotherapy and additional diagnostic CT scans. However, all the exposures would be research exposures required by the protocol.

1.2 Key Terminology for research studies involving imaging

Modality – any of the equipment or probes used to acquire images of the human body.

Dosimetry – process of calculating the absorbed dose of ionising radiation and optimising dose delivery.

Dose optimisation – process by which exposure to ionising radiation is restricted to a level which is as low as reasonably possible to achieve the diagnosis or therapeutic aim.

Dose constraint – the restriction on the prospective dose to a person, it represents an upper bound to the outcome of any dosimetry.

Statutory Duty Holders with specific roles where research exposure is planned:

- Employer – York Trust as an employer is required to hold a licence for each administration at each medical radiological installation (for example York Hospital, Scarborough Hospital) for the purpose of the administration of radioactive substances to humans.
- MPE (Medical Physics Expert) – involved in all medical exposures, including research. Has primary responsibility to advice on dose optimisation, including patient dosimetry and quality assurance. There must be a MPE at every research site. It's a legal requirement for a MPE at every research site to assess IRMER compliance locally. The advice of MPE will inform and assist IRMER compliance review at each research site.
- Practitioner – registered medical or health professional at a research site who is entitled, in accordance with the employer's procedure, to take responsibility for an individual medical exposure, including research exposures and has a primary role to justify medical exposures. There must be a Practitioner at every research site. Every practitioner is required to hold a licence in order to justify the administration of radioactive substances to humans. It's a legal requirement for a Practitioner at every research site to asses IRMER compliance locally.

MPE and Practitioner facilitate local assessment of compliance.

- Referrer – registered medical or health professional at the research site who is entitled to refer individuals for medical exposure to a practitioner.

- Operator – any person at the research site who is entitled to carry out practical aspects of the exposure.

2 Who Should Use This SOP

This SOP is relevant to Investigators, Research Teams and R&D Unit staff setting up & delivering research studies sponsored or hosted by the York and Scarborough Teaching Hospitals NHS Foundation Trust that require support from the Radiology Directorate.

3 When this SOP Should be Used

This SOP aims to cover the requirements for research studies that involve imaging and require support form the Trust Radiology services. The procedure described in this SOP should be followed when setting up and delivering research studies sponsored or hosted by York and Scarborough Teaching Hospitals NHS Foundation Trust.

This SOP also supplements the Radiology Directorate internal procedure [RA-SOP-RESEARCH] *Radiology Support for clinical research studies ('research exposure'*) as required by IRMER. Anyone involved in processing research applications involving imaging and exposure to ionising radiation and radioactive medicinal products is expected to understand their role as specified in this SOP (for Research and R&D staff) and in RA-SOP-RESEARCH (for Radiology staff).

4 Procedure(s)

4.1 Setting-up research studies that require support from Radiology Directorate (local assessment of feasibility, capacity and capability to deliver a research study).

For studies in set up IRAS submissions for approvals are facilitated through the IRAS system and a new application is created for each new research study. The project filter questions should accurately confirm whether the study will use ionising radiation, and weather the study additionally involves exposure to radioactive material. For any studies involving radioactive materials (nuclear medicine), it is responsibility of the study Sponsor to gain ARSAC approval for the study, and it is responsibility of the Investigator Site to ensure that appropriate ARSAC licences are in place for such studies (the Employer's & Practitioner's Licence with the applicable imaging authorised for research purposes).

Locally the set up of studies involving imaging is co-ordinated by the R&D Research Delivery Facilitators (RDFs) in cooperation with the study Sponsor, the local PI & Investigator Team, Modality Leads for Radiology, IRMER Practitioners and Medical Physics Expert/s (Appendix 1 & Appendix 2)):

- Research study Sponsors should determine the scope and format of due diligence required in relation to the local Radiology facilities & services. This

is likely to include consideration of the following as a minimum: (i) staff and staff training, (ii) capacity and capability of facility to deliver the required procedures, (iii) accreditation, (iv) quality assurance procedures (SOPs, quality control and audit), (v) inspection and maintenance of imaging equipment.

- RDFs will undertake initial discussions with the proposed imaging department at an early stage of study set up regarding the required due diligence and any necessary documentation to demonstrate the competence of the designated imaging service to ensure that adequate GCP requirements are met. Good Clinical Practice (GCP) is applicable throughout a research study and the general principles of GCP are applicable to imaging services (see section 4.2 for training requirements).

Particularly relevant principles are:

- *Each individual involved in conducting a trial should be qualified by education, training and experience to perform his or her respective task(s) (Section 2.8)*
- *All clinical trial information should be recorded, handled and stored in a way that allows its accurate reporting, interpretation and verification (Section 2.10)*
- *Systems with procedures that assure the quality of every aspect of the trial should be implemented (Section 2.13)*

Under IRMER the following is required when setting-up research project:

- **Research projects which involve the use of research exposures to ionising radiation** must receive favourable ethical opinion from a Research Ethics Committee (REC) before commencing. Where the Trust has been selected to participate in such study, the relevant R&D Research Delivery Facilitator (RDF) will liaise with the relevant Modality Lead to assess and confirm if the department has the capacity & capability to support the study, and if the Trust can comply with the study specific requirements as detailed in the study protocol (e.g. RECIST reporting). Further, the RDFs will liaise with the study Principal Investigator (PI), Radiation Protection Adviser (RPA) or Medical Physics Expert (MPE) based at Leeds Hospital, the relevant IRMER Practitioner to gain authorisations for a study specific IRMER Form. The aim of this form is to demonstrate that the Trust has complied with IRMER regulations in setting dose constraints and/or targets for radiation exposure for research purposes. The completion of IRMER Form is carried out taking into consideration local factors (equipment, exposure factors and clinical practice, patient related issues including age, sex and life expectancy). The IRMER Form must be authorised and fully signed prior to the study commencing (see section 4.3 for requirements and specific considerations for studies involving ionising radiation).

- For **studies which use radioactive medicinal products (nuclear medicine)** the Trust is required to hold a certificate for use in diagnosis and treatment which is issued by ARSAC – Employer's and Practitioner's licence. Checks must be performed to confirm whether the research procedure has been included for research on the Employer and Practitioner licenses. If so, no further arrangements are required to take part in a research project. RDFs will need to notify practitioners about the research protocol and the practitioner will need to confirm the capacity to perform the procedures. The

original ARSAC licences will be held within the Nuclear Medicine department in the ARSAC folder and a copy filed in the electronic study file. The RDFs will liaise with the study Principal Investigator (PI), Radiation Protection Adviser (RPA) or Medical Physics Expert (MPE) based at Leeds Hospital, the relevant IRMER Practitioner and ARSAC licence holder (Practitioner's licence holder) to gain authorisations for a study specific IRMER Form (see section 4.4 for requirements and specific considerations for studies involving administration of radioactive substances - nuclear medicine tests/ radionuclide therapy).

- IRMER does not apply to **studies which do not involve the use of ionising radiation**. For these studies seek approval for the study from the relevant Modality Lead. If Radiology approval is received, the relevant R&D Research Delivery Facilitator (RDF) will proceed with setting up the study. When the R&D Unit approves the study they issue 'Confirmation of Capacity and Capability'. The study will be added to the Radiology Spreadsheet and an electronic file will be created with the relevant study documents by a member of the R&D Team.

4.2 Training requirements

Staff involved in undertaking imaging procedures as part of a clinical research study should receive GCP training (Good Clinical Practice) and any study specific training commensurate with their roles and responsibilities. This is assessed on study by study basis, and usually required only if Radiology procedures for research fall outside of the standard practice and competencies. A record of training should be maintained for individuals involved in study specific procedures and documented in the study Investigator Site File. It's the study CI/PI's (or delegated individual) responsibility to make sure these records are complete and up to date.

The initial assessment of training requirements is carried out by the R&D Research Facilitators at a study set up stage (assessment of capacity & capability) and in accordance with the study sponsor's requirements. Most research studies are likely to involve a site visit from the study sponsor representative/s which might include visit to Radiology, or Radiology might be asked to complete a questionnaire to help the study sponsors decide if York and Scarborough Teaching Hospitals NHS Foundation Trust can host the study. Any issues regarding suitability and performance of the service during the study should be raised with the R&D Unit in a timely manner.

4.3 Requirements and specific considerations for studies involving ionising radiation:

IRMER outlines specific requirements in relation to research exposure that must be considered during protocol development and during the delivery of the study.

- Study must be REC approved;
- Voluntary consent must be received form the participant prior to any research exposure;
- Research participants must be informed in advance of the risks associated with the research exposure (PIS);
- Individual target levels of radiation dosage should be planned for research participants to receive the greatest medical benefit with minimum risk;

- Dose constraints must be in place where no direct medical benefit is expected;
- Dose constraints must be adhered to, with evidence of periodic dose audits being an acceptable form of measuring compliance;
- Practitioners should pay special attention to the justification of exposures that have no direct health benefit.

4.3.1 Dose constraints & target levels:

- Dose constraints are established for biomedical and medical research where no direct medical benefit for the individual is expected from the exposure.
- Dose constraints must be adhered to.
- Individual target levels of doses are planned by the Practitioner for patients who voluntarily undergo an experimental diagnostic or therapeutic practice from which the patients are expected to receive a diagnostic or therapeutic benefit.

IRMER principles of justification and optimisation apply to research projects. IRMER requires dose constraints to be adhered to for those individuals where there is no direct medical benefit (e.g. healthy volunteers and some patients), and target levels of dose to be planned for patients who may be expected to receive a diagnostic or therapeutic benefit from the research. Many studies involve administration of high doses of radiation to the patient. Under IRMER there is a further requirement to pay special attention to medical exposures involving the administration of high doses.

4.3.2 Dose constraints/ target levels for York and Scarborough Teaching Hospitals NHS Foundation Trust research participants:

It is a legal requirement for York and Scarborough Teaching Hospitals NHS Foundation Trust as a Research Investigator Site and/ or a Research Sponsor to set local dose constraints/ individual target levels for individuals taking part in research studies.

IRMER requires all research trials involving radiation exposures to be approved by a Research Ethics Committee. For a number of reasons, dose constraint calculations in ethics applications for multi-center studies may not be sufficient to ensure IRMER compliance at individual investigator sites; different imaging options (e.g. chest X-ray or CT scan) may be offered, and the equipment and imaging protocol (exposure factors) may not be the same across different sites.
Therefore, to ensure a study is IRMER compliant, the MPE for York and Scarborough Teaching Hospitals NHS Foundation Trust will examine the protocol, the ethics application and the patient information sheet for each study where any of the procedures in the protocol involves exposure to ionising radiation and the participants are involved in medical or biomedical, diagnostic or therapeutic, research programmes. This review is carried out using an IRMER form (Appendix 3) taking into account local factors such as the equipment, exposure factors and clinical practice, and patient-related issues, including age, sex and life expectancy. A legally binding local dose constraint will then be derived for the study.

For York and Scarborough Teaching Hospitals NHS Foundation Trust this review is coordinated by York R&D Unit Research Delivery Facilitators and carried out by:

Radiation Protection
Department of Medical Physics
The Old Medical School
Leeds General Infirmary, Leeds, LS1 3EX.
Email: leedsth-tr.medphysethics@nhs.net

The **IRMER Form** (Appendix 1) demonstrates that the Trust has complied with IRMER in setting dose constraints and/ or target levels for radiation exposure for research purposes. The IRMER form should be signed by the study PI, the Trust MPE, and the relevant IRMER Practitioner and ARSAC licence holder (where applicable), prior to the study commencing. The IRMER Practitioner will have to determine whether the radiation exposures proposed for the purposes of the research study are justified. The MPE will set dose constraints for studies where no direct benefit to the individual is expected, and considered appropriate by the practitioner.
The MPE will set a target level of dose where some benefit to the individual is expected from an experimental practice, and considered appropriate by the practitioner. The dose constraint or target level will be documented on the IRMER form, a copy of which can be found in the study file on the Applied Learning and Research drive & EDGE. **A dose constraint may not be exceeded. A target level may be exceeded if this would be of benefit to the participant**.

4.3.3. Information about risks - Patient Information Sheet (PIS) & Consent:

IRMER includes a requirement for all research participants to receive prior information on the risk of any exposures they may receive as part of a research study. Knowledge and communication of risk to research participants form an essential element of modern medical practice and without it informed consent cannot truly be obtained.

- The individuals concerned participate voluntarily in the research programme.
- The individuals concerned are informed in advance about the risks of the exposure.

The responsibility lies with:
Chief Investigator (CI) and Principal Investigator (PI): Research exposures are defined as any exposures described in the research protocol (including both the research specific and standard care exposures). It should be made explicit to participants which exposures are additional to standard care. It is the responsibility of a research study CI or PI (or a delegated individual) to ensure research participants confirm and sign an informed consent form prior to participating in the study. The process of seeking informed consent must be documented in the participant's medical records, and an on-going consent should be confirmed at every research visit.

Referrer: It is the responsibility of the referrer to ensure that the participant has consented to the research study prior to completing a referral card for a research exposure. To comply with IRMER the referrer must be a registered healthcare professional with such an entitlement given by the MEC on behalf of the Trust. Non-medical referrals will only be accepted by prior arrangement as set out in their non-medical referral agreement or as stated in the research protocol. Radiology referrer

entitlements are recorded within the Radiology SOPs and can be confirmed by contacting the relevant Modality Lead.

Please note:
Referrers and the relevant Research Teams must ensure that the request card or other agreed referral method includes a sticker or statement showing the study title allowing the operator to identify research participants. This will enable the operator to monitor that dose constraints or target levels are being adhered to by checking the levels on the IRMER form and checking previous imaging records on CPD.

4.4 Additional requirements and specific considerations for studies involving administration of radioactive substances (nuclear medicine tests/ radionuclide therapy).

An ARSAC license must be obtained to carry out research-indicated nuclear medicine procedures (e.g. MUGA and PET scans). Where research involves the administration of radioactive substances, an ARSAC licence must be held at a research site where administrations take place with the required procedures listed for research on both the Employer and Practitioner licences.

Up to 6th Feb 2018 ARSAC certificates for research were site, research study and number of cases specific. Changes for Research Involving the Administration of Radioactive Substances implemented the following:

- Under MARS, certificates were issued for each research trial. Under IRMER employers and practitioners wishing to administer a radioactive substance in accordance with a specific research trial protocol must hold authorisation for that procedure for research on their licence.
- After 6th February 2018, any valid research certificates will be considered as a licence for the practitioner and the employer at the radiological installation, to administer radioactive substances in accordance with the research trial detailed on the certificate. Existing research certificates remain trial specific and remain valid until the expiry date.
- For any new or un-certificated research trials both the employer and practitioner will require an appropriate licence to administer radioactive substances in accordance with the research protocol. Once an employer has a licence in place and there are licensed practitioners entitled under the employer's procedures, administrations can be performed in accordance with the procedures detailed in any ARSAC approved research trial that are within the scope of the licences. **The new employer and practitioner ARSAC licences for research are not trial specific**.

4.5 Additional considerations for all studies involving ionising radiation and administration of radioactive substances:

- **For patients participating in multiple clinical trials**/ research projects the risks to an individual who is involved in several research trials must be considered. It is unacceptable that an individual should repeatedly take part in research trials leading to substantial cumulated radiation dose. This is particularly relevant for normal healthy volunteers where an annual dose

constraint of 10 mSv from all research exposures (including those from non-nuclear medicine procedures) should be applied.
Investigators should always review the previous radiation exposure of the proposed participants. In the case of normal healthy volunteers, previous exposures as part of their diagnosis or treatment should not be included as part of the proposed annual dose constraint of 10 mSv.

- **Pregnancy** - the possibility of early pregnancy in connection to individuals of childbearing potential as research participants must be considered.
Individuals who are pregnant or breastfeeding must not be involved in any research trial, except where problems related to their condition are under investigation and alternative techniques that do not involve ionising radiation have been considered and rejected.

4.6 Amendments to research study protocol, procedures and documentation.

Amendments are changes made to a research study after review body approval has been received. An amendment can be either:

- Substantial; changes to the terms of the application, or to the protocol or any other supporting documentation, or,
- Non-substantial (minor); changes to the details of a trial that are administrative.

An amendment should only be implemented in the Trust once all approvals from the relevant review bodies have been received – receipt of these approvals is checked and confirmed by R&D Research Governance staff.

The relevant R&D staff should be notified (via research.qa@york.nhs.uk.) of amendments that may have impact on Radiology support for a research project. Once all of the changes have been identified, **it must be determined whether they impact on the Radiology Support for the project**:

- **If so, the relevant Modality Lead will be contacted for confirmation of continuing capacity and capability to deliver the study**.
- If no impact but a new version of the main study protocol was issued, this will be saved and superseded electronically, and the Radiology study file updated accordingly.
- If no impact on Radiology support for the study and no changes to core documents, no further actions are required.

R&D staff will ensure that:

- Radiology is able to continue to support the study taking into account; costs, workload, other resource implications and practical aspects of the study delivery, including any specific staff training that may be required.
- Radiology staff have access to all of the correct versions of study documentation e.g. protocol, relevant SOP, IRMER form that may have changed as a result of the amendment.

4.7 Urgent safety measures or safety concerns requiring a temporary or permanent halt to a study

CTIMP trials are legally regulated by the Clinical Trials Regulations. The Regulations require immediate action in the event of an urgent safety measure (USM). During the course of a study, new safety information may necessitate an immediate change in study procedures or a temporary halt to the study to protect clinical trial subjects from any immediate hazard to their health or safety.
It is the study PI's responsibility to implement USM and notify Radiology about the immediate halt to a study. Restarting a halted study is a substantial amendment.

4.8 Responsibilities of the York and Scarborough Teaching Hospitals NHS Foundation Trust when sponsoring a research project that involves exposure to ionising radiation.

- **Responsibility of the study CI in preparing a research IRAS application:**

  It is the responsibility of the Chief Investigator (CI) to clearly summarise the radiation exposures (maximum number) of each type to which each volunteer could be subjected, and to present this information clearly to both the ethics committee and the local committee responsible for approval for these exposures under IRMER.

The research study must receive ethical approval and local Trust approval of IRMER compliance prior to commencement.
When submitting an Ethics Application input must be obtained from the following experts:

- A lead Medical Physics Expert (lead MPE), who performs a dose/risk assessment for all the radiation exposures proposed in the protocol.
- A lead Clinical Radiation Expert (lead CRE), who assesses whether the protocol could involve additional radiation exposure at any site in the study and advises the CI and the main REC on the suitability and ethical acceptability of additional exposures.

During the development of the study protocol the Chief Investigator should seek advice from the lead experts at the earliest possible stage.

The dose and risk assessment should be accurately documented in the IRAS application. This should be prepared by a Medical Physics Expert (MPE) who is a registered health care professional and has expertise relevant to the planned exposures. MPEs are usually registered as clinical scientists by the Health Professions Council under the Health Professions Order 2001. Where the study involves different types of exposure (for example, both radioactive materials and other ionising radiation, or more than one imaging method), advice may need to be sought from other MPEs with relevant expertise. The lead MPE should produce a combined assessment for the ethics committee, giving the names of any other MPEs who have contributed to the assessment.

The Clinical Radiation Expert (CRE) should be a registered health professional with clinical expertise relevant to the planned exposures. Typically this might be a radiologist, a clinical oncologist (for radiotherapy) or a nuclear medicine specialist. Their assessment should cover potential exposure at all research sites, taking account of possible variation in normal clinical practice. Where the study involves

different types of exposure (for example, both radiotherapy and other ionising radiation), advice may need to be sought from other CREs with relevant expertise. The lead CRE should produce a combined assessment for the ethics committee, giving the names of any other CREs who have contributed to the assessment.

The ethical review will consider any research exposure that would be additional to exposure received by participants as part of normal clinical care if they opted not to participate in research. The main REC will consider whether the additional exposure is ethically acceptable, the risks and burdens involved in relation to the potential benefits, and the description of risk in the participant information sheet. Where there are differences between sites in radiation practice in clinical care, the main REC will need to consider whether this affects the ethical opinion.

- **Responsibility of the study sponsor (R&D Unit as the study sponsor legal representative).**

For studies involving research exposures under IRMER, the trial sponsor will require assurance that organisations hosting the study (whether NHS or non-NHS organisations) will comply with their IRMER responsibilities.

This should be addressed in the terms of the agreements between the sponsor and the host organisations. Sponsors should also ensure that local PIs are aware of the need to follow local IRMER procedures.

5 Related SOPs and Documents

International Conference on Harmonisation Guidance on Good Clinical Practice (Topic E6) (CPMP/ICH/135/95)

"Approval of research involving ionising radiation", available here: http://www.nres.npsa.nhs.uk/applicants/guidance/

http://www.arsac.org.uk/

The Ionising Radiation (Medical Exposure) Regulations 2017

The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2018

RA-SOP-RESEARCH – located on Radiology Q-Pulse (available upon request)

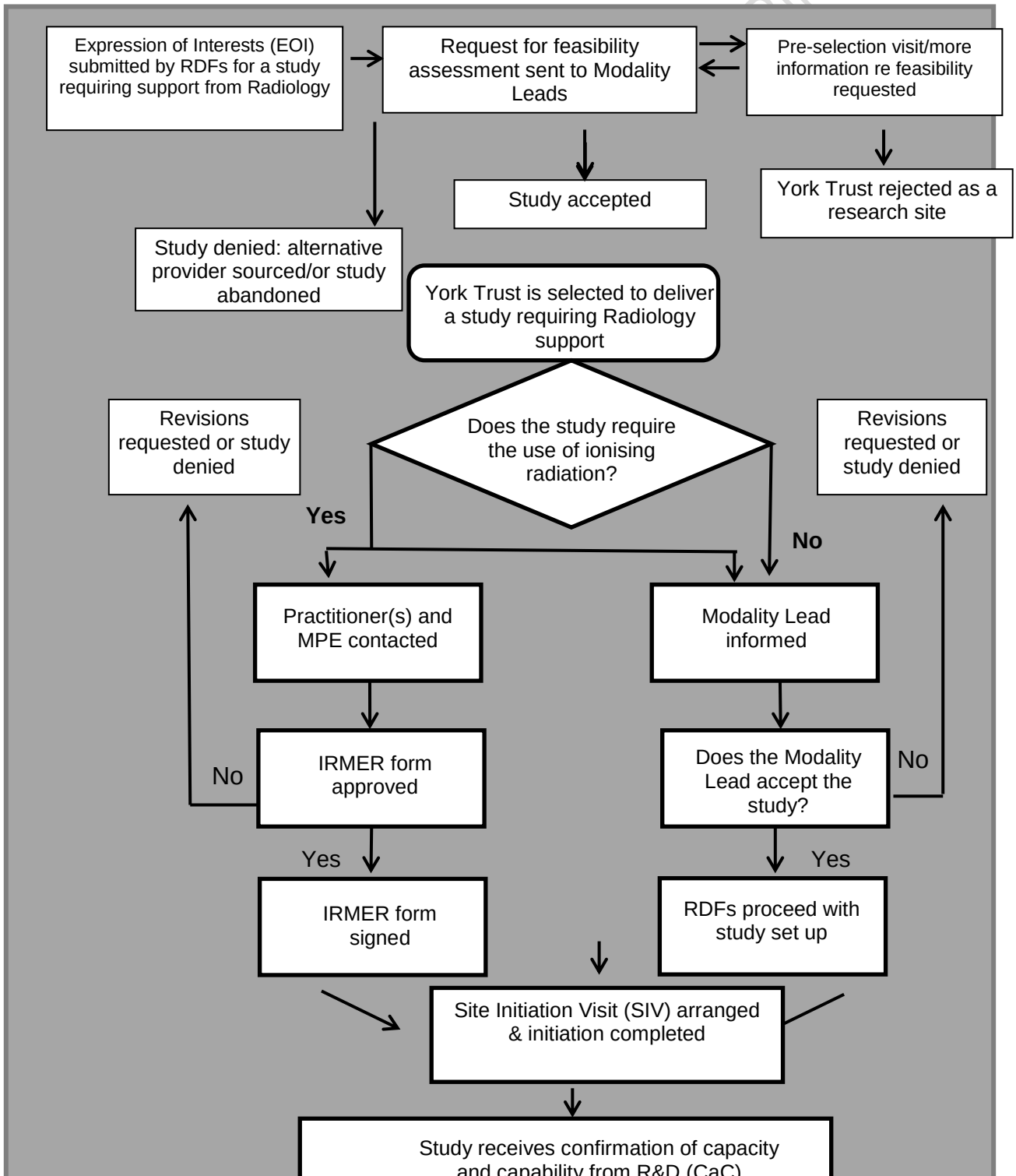
6 Appendixes

Appendix 1: Flowchart for research approval

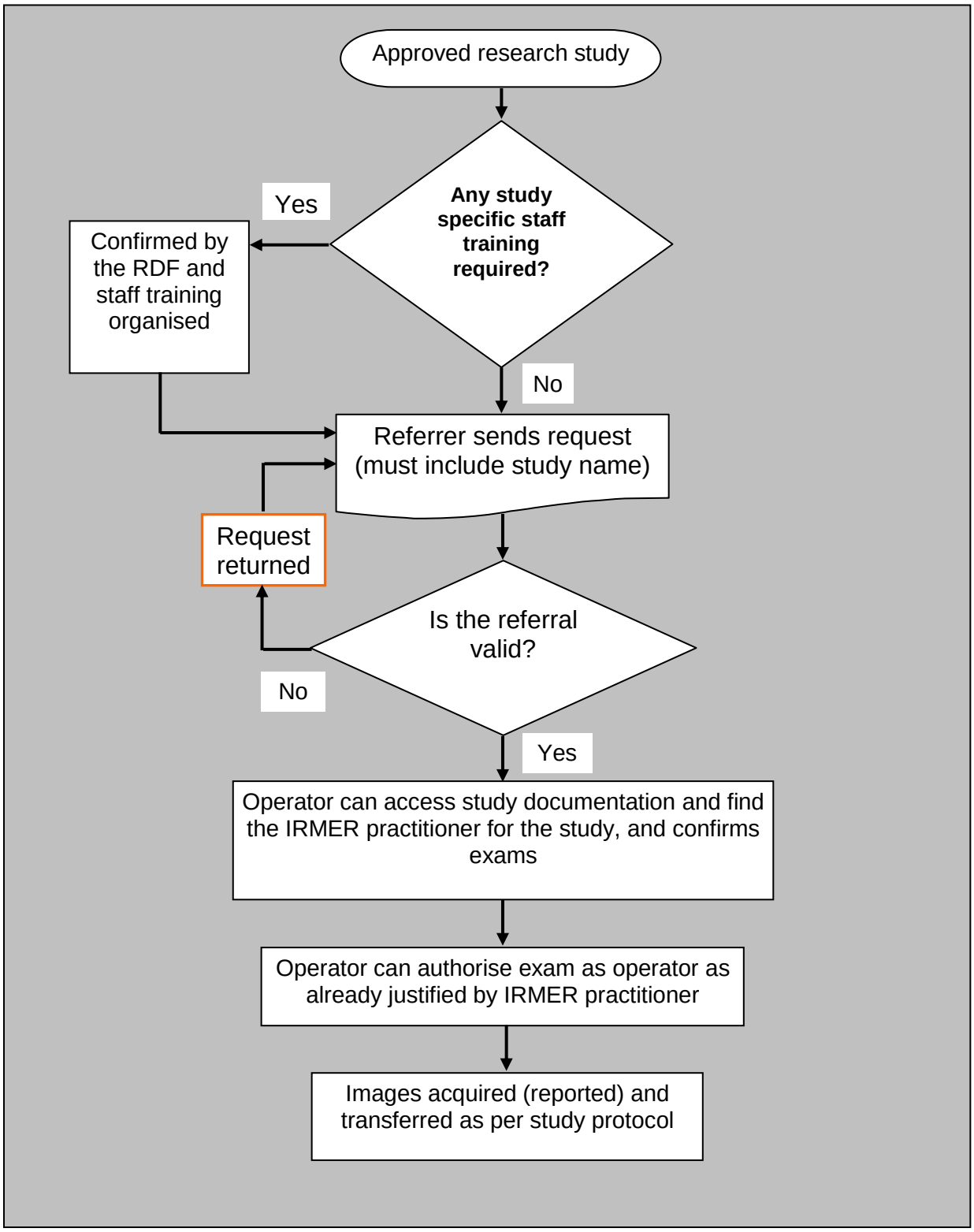
Appendix 2: Flowchart for research imaging and training

Appendix 3: IRMER Form

Appendix 1: Flowchart for research approval



Appendix 2: Flowchart for research imaging and training



Appendix 3: IRMER Form

Individuals requiring access to the current version of the IRMER Form should send a request to: research.qa@york.nhs.uk, or email leedsth-tr.medphysethics@nhs.net directly.

Please always make sure you are using the latest version of the IRMER Form. Check the 'Guidance' section of the IRMER Form for information on how to complete and submit the form.