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

Research Studies Involving 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

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Approved by:	Name/Position:	Mags Szewczyk, Research QA Manager
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	Name/Position:	Sarah Sheath, SOP Controller
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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	Reviewers	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.
4.0	14th February 2024	Richard Furnival	Change of author. Expansion of setup, delivery and administration processes in line with recent changes and updates.

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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.

This SOP will provide guidance on the R&D and Radiology Department processes for oversight of this activity throughout the duration of a trial.

This will include;

- **Study Setup - Section 4.1**
- **Study Delivery Section 4.2**

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*

Applicable Legislation

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 practitioners and employers (the new regulations replaced the certification process for the administration of radioactive substances under MARS, and lead to changes in the way ARSAC handles applications). See section 4 for more details.

- CTIMP studies (clinical trial 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 research provisions of IRMER apply to any research exposure involving ionising radiation, not only to exposures that are additional to routine care.

The Health Research Authority (HRA) are an additional regulatory authority governing the approval of all research projects with are looking to be delivered within the NHS in the UK. This includes HRA Radiation Assurance which is a review conducted centrally on behalf of all NHS Trusts to provide assurance as to the project's regulatory compliance; Radiation Assurance - Health Research Authority (hra.nhs.uk)

Key Terminology for research studies involving imaging

Modality – any of the equipment or probes used to acquire images of the human body. E.g. CT Scanner, X-Ray, MRI. Each associated Modality is overseen by a Trust Modality Lead

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.

Research Exposure - 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.

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.
- 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.

  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.

Trust Sponsored Studies – Studies whereby the York & Scarborough Teaching Hospitals NHS Foundation Trust is acting as the Sponsor/ Co-Sponsor for the research study. Such studies will come from Trust generated research questions and require the Trust to design/co-design the study and documentation.

Hosted Studies – Studies that are Sponsored by external organisations (academic institutions, other NHS Trusts, Commercial companies) whereby the Trust is acting as the Host for delivery of the trial

2 Who Should Use This SOP

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

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 Study Setup

Prior to commencing study activity within the Trust, R&D will conduct a detailed review and setup process to ensure all appropriate support, approvals and resource is in place prior to commencement. This will include working with the Radiology Department.

A flowchart to summarise study approval and Radiology review is provided in Appendix 1. The sections below provide more details on these various timepoints and processes;

4.1.1 Feasibility & Study Design

New Research projects can be identified by one of two means;

- Expressions of Interest; whereby the Trust as identified/ been approached with a Hosted Study which is of interest to the clinical team

- Home-grown research projects; whereby the research idea has been designed/co-designed by Trust employed staff, such projects will also tend to require Trust Sponsorship/Co-Sponsorship. In some cases these may be ideas generated from Radiology staff themselves.

When exploring the option of a new research study R&D will conduct a feasibility review to look to ensure all possible support and infrastructure is available to deliver the potential project, where ionised radiation involvement is required, this will include the Radiology Department

For Trust Sponsored studies involving ionised radiation, Radiology Department support will additionally be requested for input into study design and the regulatory application process (please see section 4.1.1.2)

4.1.1.1 Assessing feasibility to deliver a future study

The R&D Unit will look to establish contact with the Radiology Department to discuss imaging feasibility and input at as early a point as possible.

In some cases it may be the Radiology Department themselves have an idea for their own research project, in such cases they can contact yhs-tr.research.enquiries@nhs.net to discuss support and next steps. In either case the following process will still apply with regards Radiology feasibility

The nature of this contact will vary based on the study type;

- Trust Sponsored Studies: The CI should make contact with the relevant Radiology Modality Lead(s) as soon as it is conceived that the study will require radiological imaging input and support. R&D/CI will invite the Radiology Department for input in the research grant application, study protocol design and the IRAS application;

- Hosted Studies: The R&D Department will contact the relevant Radiology Modality Lead(s) as soon as it is confirmed that the Trust have been selected to deliver the Study.

  In some cases, Radiology Department input may be sought at an earlier stage should there be a part of the feasibility review R&D need clarification on prior to expressing interest in the trial (e.g. querying if certain types of imaging are delivered in the Trust or if local equipment information is required). In such cases they will contact the Radiology QA Officer to query this information.

In either case the Radiology Modality Lead(s) will be reassured by R&D that at this early stage of the process only general feasibility to deliver the project will be requested.

Due to the nature of research applications, study timelines, documentation, imaging schedules and resource needs are often subject to alterations and delays. Whilst local staff and equipment capacity can change over time also. As such, approvals at this stage will be considered non-committal in terms of capacity and resources from the Radiology Department, and further approvals will be requested once the study timelines have been confirmed and the study setup process begins in full (see section 4.1.2.1).

4.1.1.2 Ionised Radiation Information on IRAS Applications - Trust Sponsored studies

Prior to commencement of any clinical research studies within the NHS all Trust Sponsors must seek national regulatory approval via the Health Research Authority (HRA); this is application is submitted via the Integrated Research Application System (IRAS).

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 regulations.

Where the Trust is sponsoring such studies where radiology support is required the R&D Department will liaise directly with the Trust's MPE staff for the completion of relevant sections of the IRAS form and associated study documents.

Key points to ensure are completed and checked with IRAS application involving Ionised Radiation are as follows;

- The project filter questions should accurately confirm whether the study will use ionising radiation, and whether the study additionally involves exposure to radioactive material.

- Details of the quantity and frequency of scans that will need assessing for the participant's duration on the trial.

  This should also include optional or conditional scans that may be required based on the participant's journey; for example extra imaging for patient randomised to certain arms or additional safety scans for participants who meet certain criteria.

- Estimated procedure dosages for the above scans documented to National Diagnostic Reference Levels. This should be completed by a Trust Medical Physics Expert (MPE)

- Details of whether the above scans would be additional to what the participant would receive if not on the trial, and if this would be case details of additional radiation risks and how these have been considered alongside the potential benefits of the research. This should be completed by a Trust MPE.

- Other patient specific considerations; such as if the scans will be completed on pregnant/lactating women or children.

Prior to submission the Ionised Radiation Section of the IRAS application will need electronic authorisation by the Trust's Lead MPE; or appropriate deputy.

4.1.1.3 ARSAC Sponsor License

Where the study is Trust Sponsored and involves the administration of radioactive substances, the Trust may additionally be required to put in place an ARSAC Sponsor License to govern their oversight of this activity for all Trust sites who Host the study.

As per ARSAC guidance a Sponsor License must be obtained if the protocol;

- requires the administration of radioactive substance
- specifies the frequency, activity or processing for an administration that would otherwise be considered standard care

However, would not be required where;

- the protocol does not specify any administrations of radioactive substances
- the only administration of a radioactive substance mentioned in the protocol is an inclusion criterion that would be received by all participants as part of

standard care, for example, a trial where all participants must have received a radioiodine therapy to be considered eligible

Further details on the application process is available here; How and when to submit research applications to ARSAC - GOV.UK (www.gov.uk)

It should be noted that ARSAC Sponsor licenses come at a charge and as such this cost should be factored into grant applications and study costings. The various charges are as follows;

- multi-centre studies: £350
- single-centre studies: £300
- low dose studies (<1mSv total participant dose): £200

4.1.1.4 Sub-Contracting & Outsourcing

If following Feasibility review it is determined that the Trust Radiology Department cannot provide the required support for the study, the R&D Department may choose to explore the option of a Sub-Contract agreement with an external organisation (e.g. neighbouring NHS Trusts, private healthcare providers, academic research sites)

In such cases R&D will arrange for a Sub-Contract agreement which will detail the responsibilities and services provided by the organisation. If required a Trust template is available here; R&D/T12

It will remain the Trust's responsibility to complete any relevant IRMER or ARSAC applications

4.1.1.5 Radiotherapy & Interventional Nuclear Medicine trials

For studies which require the involvement of Radiotherapy or other interventional nuclear medicine, the R&D Department will be required to establish the support of the associated Trust sites regional provider in line with the Yorkshire & Humber shared care agreements.

For such activity it will be expected by HRA and IRMER regulations that the supporting NHS Trust site are opened as full Treatment Site for the study included their own Confirmation of Capacity & Capability approval, site agreement with the Study Sponsor and IRMER/ARSAC applications where required.

As such the R&D Department will make contact with the supporting Trust's Research Department to ascertain their capacity to support this activity and confirm that they will be opening the trial.

For such trials, the Treatment Site must be activated for study activity by the Study Sponsor before YSHFT can provide their own activation and commence recruitment.

4.1.2 Local Authorisations

With feasibility confirmed and necessary Trust Sponsor-related applications submitted, the study will now commence active set-up within the Trust. It is at this point when the R&D Department will commence its Confirmation of Capacity & Capability (C&C) Process.

Full details of this process are available at R&D/S14, details pertinent to the Radiology Department are outlined below;

4.1.2.1 Radiology Modality Lead Approvals

As part of the C&C process the R&D Department will contact the relevant Radiology Modality Lead(s) to seek their approval for the study to proceed to open.

As detailed in Section 4.1.1.1 the R&D Department will have already established initial feasibility discussions about the study to ensure to the study is generally feasibility, however it is now at this point where the R&D Department will request that the Modality Leads confirm their capacity and authorisation for the study to now proceed ahead towards study opening.

Prior to contacting the Modality Lead for approval, the R&D Department will obtain the following;

- Confirmation from the Study PI as to how the studies imaging schedule may fit or differ with Trust Standard of Care for the patient group
- Confirmation of the studies Participant recruitment target
- The full Local Information Pack from the study sponsor; including imaging related documentation and if required a copy of the study ARSAC license
- Confirmation of any costings provided to the Radiology department to cover this work, where provided

R&D will send a request for radiology authorisation via email to the Modality Lead(s) providing all the above information plus additional supporting information that may be relevant to the department

During their review the Radiology Modality Lead(s) should consider the following;

- Frequency and intensity of the imaging alongside the duration of the study and anticipated participant numbers; measuring the impact this will have on clinical capacity and scanner space.
- Additional reporting requirements that may impact on capacity and resource; for example, RESIST reporting, or if the radiologist/radiographer may be required to provide additional data
- Confirmation that the necessary equipment requirements are in place.
- Additional training needs that may be required of their staff for delivery of the Research Exposure
- In the case of PACS where images are to be processed and sent to an external organisation, that image sending requirements are achievable

and that the department has the capacity to manage the volume of images anticipated.

The Radiology Modality Lead will confirm by email their authorisation for the study and should they require further information or have any questions about any of the exposures or study activity R&D will enquire about this on their behalf with the Study Sponsor.

In some cases, the Ionised Radiation activity for the study may fall in line with Standard Care imaging scheduling for that patient group (this would be confirmed by the study PI) and therefore will not bring additional workload for the Modalities. In such cases the R&D Department will still send a notification email to the Modality Leads to make them aware of the study, however no further Authorisation will be requested.

4.1.2.2 IRMER Application

Whenever Ionised Radiation exposures are present within a Study Protocol and IRAS Application the Trust will be expected to complete an MPE authorised IRMER Form for the named study.

An IRMER form should still be completed even when all exposures are in-line with Standard of Care; this is important as the trial may still bring additional considerations that may impact on exposure risk which the MPE may need to review; for example, a trial introducing new or more intensive chemotherapy exposure to a cancer patient that may increase radiation risks.

At York & Scarborough Teaching Hospital NHSFT, the IRMER form review is facilitated on the Trust's behalf by the Medical Physics Department at Leeds Teaching Hospital NHSFT (Leeds Med Physics). Leeds Med Physics will review exposure information on the Trust's behalf ahead of returning for Trust MPE and PI authorisation.

The R&D will prepare and follow-up the IRMER Form on behalf of the Trust and will liaise directly with Leeds Med Physics.

The Process for IRMER completion will be as follow's;

i. Once setup of the study commences following initial feasibility discussion with Radiology, R&D will prepare a new IRMER form with relevant information copied over from IRAS form and Study Protocol
    - The template copy of current version of the IRMER form (v1.9 dated 30/11/2017)
    - Radiation dosage information can be found in 'Part B Section 3' of the IRAS application form, R&D may choose to copy this over but if unsure can be left for Leeds Med Physics to complete (who will check this information as part of their review regardless)

ii. Once the form has been prepared by R&D it will be sent by email to Leeds Med Physics (leedsth-tr.medphysethics@nhs.net) who will start their review. The following documents must also be sent alongside this form;
    - Study Protocol
    - IRAS Application Form

- Participant Information & Consent Documents
- HRA and REC Approval Letters (when available, the application can start without these but must be present prior to sign off)
- Imaging Manuals and other Radiology technical documentation for the study
- Sponsor and Trust ARSAC License (where Radioactive Materials are part of the study)

iii. Leeds Med Physics will now commence their review and measure exposures risks for the study. Once confirmed the partially signed IRMER form will be returned to R&D for final sign-off

iv. R&D will forward the partially signed form to the Trust MPE license holder for signature in 'Section 2. Approval Of Project By The Trust' alongside each of the relevant sub-sections.

v. Upon Trust MPE signature the form will finally be sent for Principal Investigator for their signature in 'Section 1 General Declarations'.

Upon completion an electronic copy of the form will be filed within the R&D shared folders, Radiology Research Shared Folders and the project EDGE records, with a paper copy filed within the Investigator Site File (ISF)

4.1.2.3 ARSAC Employer & Employee License

Where the study involves interventional or diagnostic nuclear medicine procedures listed within the study IRAS form, R&D must check that these are covered by the Trust's ARSAC Employer license

R&D should cross reference Section A1 of the IRAS Form with the Employers License ensuring that the investigation and chemical form is cover. R&D may consult a Trust MPE holder for confirmation of this if unsure.

It should be noted that York Hospital and Scarborough Hospital hold separate licenses for each site and must both be checked in turn as relevant for the study. MPE Employee Licenses for the hospitals named MPE must similarly be checked.

Should the investigation not be listed on the Employer ARSAC license an amendment may be an option to include it. However, as the Employer License includes all feasible investigations the Trust can deliver if an investigation is not listed this will likely mean that Trust will not have the capability to deliver it and as such may need to withdraw from the study. Should R&D wish to explore this option they must contact the Radiology Clinical Director, Radiology QA Manager, and site MPE to begin this discussion.

4.1.2.4 Radiology Research Folder

During setup R&D will create a new Project Folder within the Radiology Research shared drive. Each project folder will contain the following documents;

- Study Protocol
- Radiology Authorisations confirmations
- The completed IRMER form and/or ARSAC amendment.

- Study Amendments relevant to radiology (please refer to section 4.2.1.2 for more information on this)

The study will also be logged on Radiology Spreadsheet as 'In Setup'

4.1.2.5 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.

4.1.2.6 Confirmation of Capacity & Capability

Upon completion of the above processes and following the addition local authorisations as detailed in R&D/S14, the R&D Department will issue Confirmation of Capacity & Capability to the Study Sponsor. This, alongside Sponsor Greenlight, will enable research activity to commence.

Once the study is fully activated this will be logged on the Radiology Research Log by R&D

2. Study Delivery

The following processes relates to the ongoing delivery and oversight of studies involving ionised radiation following their activation.

This includes any subsequent amendments to the study design, safety monitoring and Trust Sponsorship considerations;

4.2.1.1 Notifying R&D of any Radiology delivery or capacity issues

If during the course of the project Radiology may encounter any issues or barriers that may limit or prevent their capacity to continue providing support for

the Study (for example imminent staffing shortages or imminent changes to scanner availability), the R&D Department should be contacted as soon as possible via yhs-tr.radiologyresearch@nhs.net

The R&D Department will notify the study PI (or CI if Trust Sponsored), Research Team and R&D QA team. The issue may be discussed further with the Study Sponsor, Radiology QA Manager and Radiology Clinical Director to see if there is a way to mitigate the issue in any way. For example, if the activity can be moved to an external organisation, or if the Sponsor is agreeable that the investigation can be negated without risk to participant safety or research data quality.

Whilst the issue is investigated, R&D will temporarily log the Study as 'Suspended' on R&D records and any <u>further participant recruitment must be halted with immediate effect.</u>

Unless otherwise advised by Research QA, Research Teams <u>should continue Follow-up activity on participants who are already enrolled in the Study</u>.
This activity may be imperative to monitoring and maintaining the participants safety whilst on the trial and as such the Trust will have a duty of care to continue this.

In the event of no resolution being available for the issue, R&D may be required to seek an early withdrawal from the study. In such cases R&D will notify the Study Sponsor and the study will await a future Close-Out

4.2.1.2 Amendments to research study protocol, procedures and documentation.

Amendments are changes made to a research study after review body approval has been received.

As per HRA categorisation, an amendment can be either:

- <u>Category A</u>; an amendment to the study design and associated documents which has potential implications to <u>all Trust's</u> capacity and capability to continue delivering the study
  e.g. adding addition scans to the imaging schedule

- <u>Category B;</u> an amendment to the study design and associated documents which has potential implications to <u>some Trust's</u> capacity and capability to continue delivering the study
  e.g. changing the imaging schedule but for only sites delivering a certain Arm of the study

- <u>Category C</u>; an amendment to the study design and associated documents which has no implications on the Trust's capacity and capability to continue

delivering the study
e.g. updating study contact details or changes to the study schedule for activity not delivered by NHS Trusts

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 yhs-tr.radiologyresearch@nhs.net) 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.

4.2.1.3 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.

4.2.1.4 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.

Where the Study involves Radioactive Material a copy of the Hosting Sites ARSAC License should also be requested and kept on file within the Trial Master File (TMF)

4.2.1.5 Radiology Referral Agreements

For some studies with a higher volume of imaging requests R&D, Radiology and the PI may determine that it would be appropriate and beneficial for a Medical Referral Agreement to be put in place to allow for Research Nurse staff to make requests for imaging scans as per the authorised study protocol.

The benefits of such may allow for reduce the burden on the clinical staff for requesting such scans as well as ensuring a streamlined pathway where Research scan windows may be tighter than the standard requesting time

The agreement will only allow for scheduled scans as per the Study protocol, this will not authorise Research staff to request any unscheduled or conditional imaging which must always be at PI/Clinician request.

Each agreement must be for a named staff member and the named study must be listed (the application may include multiple studies where appropriate)

Should the PI and R&D wish to explore this option they must follow the following process;

I. The PI and identified Research staff member must discuss with the staff members managing Senior Research Nurse (SRN) member who should consider the experience, competencies and appropriateness of such work prior to agreement.
II. Once agreed the Research Team should complete a Radiology Referral Agreement form (Appendix 3 and available upon request from yhs-tr.radiologyresearch@nhs.net). During this application the Research Team will be asked to justify the need for such referrals and will be asked to identify the specific scans they wish to refer.
III. Upon completion of the form should be returned to R&D via yhs-tr.radiologyresearch@nhs.net
IV. R&D will then pass the application onto the Radiology Quality Management team who will review and seek approvals from the appropriate Radiology leads. The Radiology leads may request for further information or justification from R&D where necessary
V. Once agreed upon the agreement will required final sign off from the study PI, Head of R&D and the Trust's Medical Exposures Committee
VI. The fully signed form should be filed within the Radiology Research shared drive with a copy filed in the Study ISF

The term of the agreement will be the length of the study unless otherwise stated. When making requests the Research staff member is expected to adhere

to the Trust's imaging requests guidance and policy's; this will be confirmed by Radiology upon completion of the form.

5 Related SOPs and Documents

ICH E6 (R2) Good clinical practice - Scientific guideline | European Medicines Agency (europa.eu)

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)

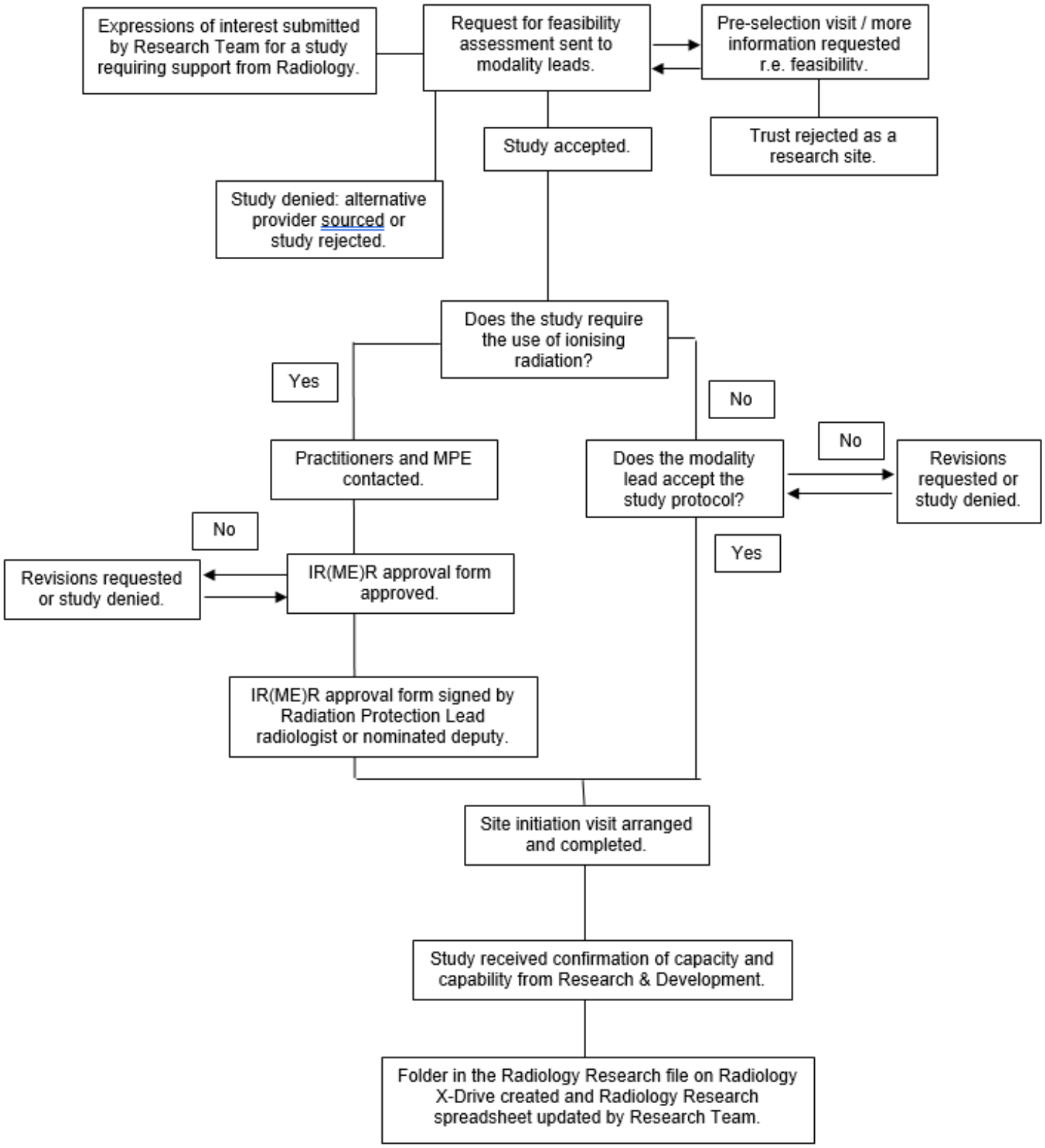
6 Appendixes

Appendix 1: Flowchart for research approval

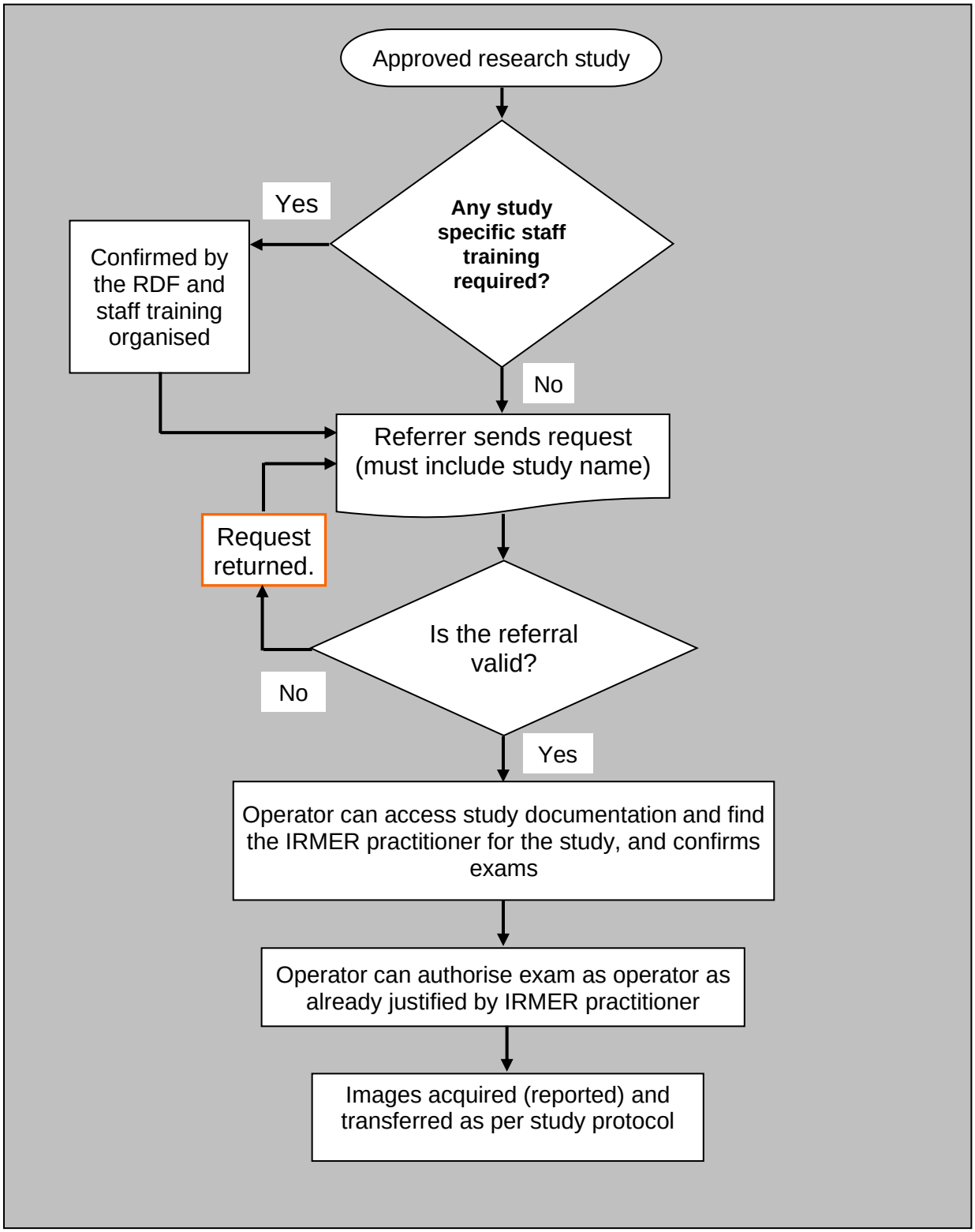
Appendix 2: Flowchart for research imaging and training

Appendix 3: Radiology Referral Form

Appendix 1: Flowchart for research approval



Appendix 2: Flowchart for research imaging and training



Appendix 3: Radiology Referral Application Form

Radiology Referral Application

The following scope of agreement is accepted by the Trust as appropriate referral practice:

Category of registered health care professional:	▪
Referring dept:	▪
Modalities included	**Examinations**
▪ **Please list**	▪
Exclusions:	▪
Why is this agreement needed?	
Is the report going to the patient's consultant/ GP or to the non-medical referrer (i.e. how is the booking to be made)?	

Radiology to issue for use by referrers

Referral short code:	

Continued…

I approve the implementation of this agreement for and on behalf of the referring department or service.

Agreement's medical sponsor (or Clinical Lead)

Signature: *

Print name: *

Job title: * Date:

Directorate Manager (or Business/ Practice Manager)

Signature: *

Print name: *

Job title: * Date:

Send this [unsigned draft proposal] or [final signed agreement] to Radiology to action

I approve the implementation of this agreement for and on behalf of the **York Trust Medical Exposures Committee (MEC)**.

Signature:

Print name: Date:

Implementation date:

Radiology check list	Master copy on QP		Signed off by:
	Electronic copy to manager		sig:
			date:

Referrer application under:

Radiology Referral Application

A Radiology referrer entitlement is conditional on each potential referrer and their Service completing parts 1-3 of this form.

Part 1: Referrer's details

Referrer's full name:		
Signature:		Registration number:
Job title:		
IRMER evidence attached:	**Yes / No** (delete or circle)	

Part 2: DM or Clinical Lead approval

Their DM or Clinical Lead name:	
Signature:	Date:
Job title:	

Part 3: Relevant clinical training completed

Their clinical sponsor's name:	
Signature:	Date:
Job title:	

Return for Radiology to action

For Radiology use:

IRMER trainer: (or external training body)	
Date of completion	
Signed for Radiology:	
Print name:	
Job title:	

CPD exams assigned (if applicable)	Y / NA / TBA
Name on database:	
Entitlement sent:	
Initials:	
Date:	