Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Clinical Research & Innovation Office

STANDARD OPERATING PROCEDURE

The Use of Radiation in Research

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Related SOPs			

Approved by (name & role)	*Dr Dipak Patel* *Associate Director R&I*	**Date:**	*17 Jul 2023*
Signature:			

Standard Operating Procedure: Clinical Research & Innovation Office

The Use of Radiation in Research

This SOP has been produced in accordance with the following:

- The Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R) and subsequent amendments
- The Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments
- The Ionising Radiations Regulations 2017 (IRR17) and subsequent amendments
- Notes for Guidance on the Clinical Administration of Radiopharmaceuticals and Use of Sealed Radioactive Sources (ARSAC[1] Guidance Notes)
- Human Medicine Regulations 2012
- The HRA's Radiation Assurance process[2]

This SOP will outline the procedure for gaining the appropriate permissions at Sheffield Teaching Hospitals NHS Foundation Trust (STH) to carry out research that involves the use of ionising radiation where:

i) the ionising radiation exposure is the subject of the research
ii) the ionising radiation is associated with diagnostic imaging or forms part of the standard treatment or therapy for the participants
iii) trials involving administration of any radioactive substances

Acronyms

AML	Alliance Medical Limited
ARSAC	Administration of Radioactive Substances Advisory Committee
CCO	Consultant Clinical Oncologist
CCTC	Cancer Clinical Trials Centre
CI	Chief Investigator
CRE	Clinical Radiation Expert
CRIO	Clinical Research & Innovation office
CT	Computed Tomography
CRF	Clinical Research Facility
DXA	Dual Energy X-Ray Absorptiometry
HR-pQCT	High Resolution peripheral Quantitative Computerised Tomography
HRA	Health Research Authority
IRAS	Integrated Research Application Systems
IR(ME)R	Ionising Radiation (Medical Exposure) Regulations
LP	Local Practitioner
MIMP	Medical Imagining Medical Physics
MPE	Medical Physics Expert
MRI	Magnetic Resonance Imaging
PI	Principal Investigator
PRA	Preliminary Research Assessment
PIS	Patient Information Sheet
RA	Radiation Assurance
RAREF	Radiation Assurance Research Exposure Form

[1] Administration of Radioactive Substances Advisory Committee
[2] https://www.myresearchproject.org.uk/help/hlpradiationassurance.aspx

REC	Research Ethics Committee
RMS	Research Management System
SOC	Standard of Care

Background and National Context

The Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R) govern the exposure to ionising radiation of patients or other persons voluntarily participating in medical or biomedical, diagnostic or therapeutic research programmes. Procedures involving ionising radiation include: diagnostic X-rays, DXA scans, CT scans /high resolution peripheral quantitative computed tomography (HR-pQCT), radiotherapy (including Brachytherapy), interventional radiography or cardiology, therapy using unsealed sources and radionuclide imaging (including diagnostic imaging and in vitro measurements).

Magnetic Resonance Imaging (MRI) or ultrasound investigations do **not** involve ionising radiation.

IR(ME)R places responsibilities on:

- The NHS Trust, or other responsible employer at each research site, represented by its Chief Executive.
- Researchers requesting examinations or treatments involving ionising radiation for the purposes of research.
- Practitioners justifying and authorising individual research exposures.
- Operators who authorise exposures under delegated authorisation procedures as agreed by the practitioner.
- Operators carrying out medical exposures for the purposes of research.

IR(ME)R requires that any "research exposure", even if it is considered standard of care (SOC), is reviewed and approved by a Research Ethics Committee (REC).

Trials involving administration of radioactive substances must be approved by an expert committee: Administration of Radioactive Substances Advisory Committee (ARSAC), in addition to gaining REC approval. This process is independent of the REC approval process but it can be undertaken in parallel with it. **Where STH is the Sponsor** for a study involving the administration of radioactive substances or projects where we specify the frequency; activity; or processing for an administration that would otherwise be considered SOC, **the Clinical Research & Innovation Office (CRIO) must obtain ARSAC research approval** before the trial can be opened and patient recruitment begins. ARSAC approval is not required when only administration of a radioactive substance mentioned in the protocol is an inclusion criterion that would be received by all participants as part of SOC.

An NHS REC will review radiation dose and risk assessments performed by the following experts:

- Medical Physics Expert (MPE) who is a Registered Clinical Scientist registered with the Health and Care Professions Council and has expertise relevant to the planned exposures.
- Clinical Radiation Expert (CRE) who is either a registered clinical radiologist, a registered clinical oncologist, registered doctor or dentist or other medical practitioner with clinical expertise in one or more modalities (imaging/treatment method) used in research studies.

At STH, local permissions are sought from the Principal Investigator (PI) or Chief Investigator (CI), an MPE, a CRE and capacity and technical checks with the Imaging Section Heads.

The gate keeper sign-off that provides Trust assurances that IR(ME)R is complied with is the electronic approval sign-off on the Research Management System (RMS) by a competent MPE, email approval by a competent CRE uploaded to the document repository (currently Alfresco) and electronic sign off provided by the MIMP Research Coordinators on RMS.

The MIMP Research Coordinators sign off on RMS also confirms that all other MIMP approvals are in place. If a PRA form has been submitted to ARSAC, the MIMP Task on RMS cannot be signed off until the ARSAC approval document has been uploaded to Alfresco by CRIO.

MIMP staff may be the competent MPE or CRE at STH to review compliance with IR(ME)R for procedures using ionising radiation that are organised by a different service provider.
Services provided by Non-MIMP providers but where MIMP Staff may be involved in IR(ME)R compliance include:

a) *PET/CT Scans; the service provider is Alliance Medical Limited (AML))*
b) *DXA and HR-pQCT scans: Service providers are the Academic Unit of Bone Metabolism, at The University of Sheffield, CRF, NGH. (CRE are Non-MIMP staff)*
c) *Vascular/Cardio Angiography (CRE are Non-MIMP Staff)*
d) *Dental x-rays (CRE are Non-MIMP staff)*
e) *Radiotherapy*
f) *PET MRI Scans*

Where research involves the use of a number of different ionising radiation medical exposures then review may need to be undertaken by a number of MPEs and/or CREs as an individual MPE or CRE may only be qualified and experienced to advise on one modality. Where MIMP staff are competent to review all the ionising radiation medical exposures then MIMP will coordinate the review.
However, where radiation is involved that is outside the competencies of MIMP staff (for example DXA imaging or Radiotherapy where therapeutic ionising radiations are involved) where the CRE are non-MIMP staff, then further coordination of sign-off is required by the study or CRIO Coordinator.

Definition

This SOP defines the steps that must be taken either by the CI, PI, Study Coordinator or CRIO Coordinator to ensure that IR(ME)R is complied with and ARSAC approval is sought when applicable where STH is Sponsor.

The SOP covers all possible ionising radiation medical exposures and processes for **both** Lead MPE and CRE assessments and Local MPE and CRE assessments. Both Lead and Local Site MPE and CRE assessments incur a cost and there may be additional costs associated with changing existing environmental permits or ARSAC licences if new or novel radiopharmaceuticals are involved in the study which are not currently used in the Trust.

Procedure

1. Lead MPE/CRE Assessment for trials where STH is the lead site (see section 1.13 for studies undergoing the HRA Radiation Assurance Process)

1.1. Chief Investigator, Directorate Coordinator or CRIO Coordinator describes all ionising radiation exposures that could be performed in the course of a research project on the current version of the MIMP form. The exposures considered standard of care (SOC) and those additional must be identified. Other imaging procedures that do not involve radiation need to be included on the MIMP form e.g. MRI and Ultrasound. Even where a research project may result in less ionising radiation exposures, compared to SOC for a patient, all exposures must be recorded on the MIMP form and assessed by competent MPE(s) and CRE.
1.2. For those services not provided by MIMP (PET/CT, DXA/HR-pQCT, and some Radiology), the CRIO or Directorate Coordinator should contact those providers at this stage (see Appendix 2 for current list of specified contacts).
1.3. Chief Investigator, Directorate Coordinator or CRIO Coordinator submits the completed MIMP form together with a Protocol and Participant Information Sheet (PIS) to the MIMP Coordinators.
1.4. MIMP Coordinators will inform Chief Investigator, Directorate Coordinator or CRIO Coordinator of any additional information / clarifications required.
1.5. MIMP Coordinators will inform the applicant if MIMP staff are not competent to review all radiation exposures in a protocol and may provide information on who else in STH may be the competent MPE/CRE.

1.6. The MIMP Co-ordinators will forward the documentation to the appropriate MPE(s) and CRE(s) who will each complete their own assessments.
1.7. MIMP Coordinators will provide the costs via email for MIMP's activity in reviewing the protocol and completing a lead MPE / CRE assessment and will upload this to Alfresco.
1.8. Chief Investigator, Directorate Coordinator or CRIO Coordinator will confirm to MIMP Coordinators that funding is available to cover MIMP's activity.
1.9. The MPE will provide the recommended wording for inclusion in section B of the IRAS application and risk statement in the PIS based on the HRA's generic statements. The MPE will also comment on suitability of wording of radiation risk in the PIS in relation to patient cohort.
1.10. The CRE will assess whether any of the exposures listed in the trial protocol are considered to be additional to SOC and inform whether they believe the nature and frequency of imaging is appropriate (i.e. justified) for the trial patients. Where the MPE/CRE has fallen outside of MIMP, the CRIO Coordinator organises the necessary sign off in RMS to indicate MPE/CRE review and approval.
1.11. The Chief Investigator, Directorate Coordinator or CRIO Coordinator may input details into the IRAS form and request electronic authorisation through IRAS from the appropriate MIMP staff identified in the information provided in section 1.7 above. Alternatively, the Lead MPE / CRE may do this.
1.12. The Research Ethics Committee review section B of the IRAS form and the risk statement in the PIS and give their approval that the ionising radiation exposures are ethical.
Where the study involves administration of radioactive materials, ARSAC will review the documentation (see section 2.0) and feedback any comments on statements in the PIS or identify and seek clarification on any inconsistencies with the information relating to these exposures.
1.13. Radiation Assurance (RA) is a UK wide process fully managed by the HRA on behalf of all four UK nations for studies which are taking place in NHS/HSC secondary care settings. It coordinates the lead MPE and lead CRE reviews in Part B section 3 of the IRAS form. This process may be Self-Managed or HRA-managed. Further guidance on the RA process can be found on the HRA technical assurances pages (https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/technical-assurances/radiation-assurance/applying-radiation-assurance/). Where MIMP are providing the lead assessment for RA but the request for the assessment comes via, or needs to follow the HRA RA process, follow the section above, and, as well as completing a MIMP Form following the steps from 1.13.1.
    1.13.1. All of the exposures should be recorded on the HRA's Radiation Assurance Research Exposure Form (RAREF Form), accessed through the RA pages on the IRAS website. The process is outlined on the HRA website https://www.hra.nhs.uk/about-us/committees-and-services/technical-assurances/radiation-assurance/applying-radiation-assurance/
    1.13.2. The MPEs and CREs within MIMP are able to review both self-managed and HRA managed studies.
    1.13.3. Applicants should specify to the HRA that STH CREs/MPEs should undertake the review where possible.

2. Submissions of New or Amendments of applications to ARSAC where STH is Sponsor

2.1 The CRIO Coordinator creates a preliminary research assessment (PRA) form in IRAS for a study that involves the administration of radioactive substances. The PRA form is automatically generated by answering 'Yes' to 'does the study involve exposure to radioactive materials?' in the Project Filter question set in IRAS. For amendments, whereby ARSAC approval is a new requirement for the trial, then the Project Filter questions of the IRAS Form will need to be amended in order to create a PRA Form for submission.
2.2 The CRIO Coordinator works with the CI and/or the CRE to complete or update this form.
2.3 The PRA Form is electronically signed in all sections in IRAS by the MPE, CRE and Sponsor.
2.4 The CRIO Coordinator should then submit this form to ARSAC by creating a New Research Application on the ARSAC online portal at the same time as the IRAS Form is submitted to REC via IRAS. The CRIO Coordinator will need to create an account if they do not have one already.

2.5 The CRIO Coordinator should ensure all required questions have been answered then subsequently attach the PRA form and a copy of the participant information sheet (PIS) when submitting to ARSAC.

2.6 If the study has gone through the HRA radiation assurance process then the F1 of the research exposure form should also be attached. For self-managed Radiation Assurance, a form similar to the F1 should be submitted. The STH MIMP Research Co-ordinators will liaise with the MPE/CRE in order to provide the CRIO Coordinator with this.

2.7 The protocol is only required for studies involving therapeutic nuclear medicine procedures (for example targeted radionuclide treatment).

2.8 Once ARSAC receives the application, details on how and when to pay the fee will be provided depending on the type of study and your preferred payment method. The CRIO Coordinator should ensure there is sufficient funding to support this application.

2.9 For amendments to ARSAC, the CRIO coordinator should notify ARSAC of any changes to a study involving the administration of radioactive substances because this may affect the approval granted. Changes include:

a) changes to the number of administrations of radioactive substances from Section A1 of the original PRA;
b) addition or removal of a procedure involving the administration of radioactive substances;
c) addition of a new study population with a different clinical condition (including changing of the age of participants);
d) addition of a new study population with a different clinical condition (including changing of the age of participants);
e) addition of healthy volunteers receiving administrations of radioactive substances;
f) changes to the radiation risk information in the PIS following changes to the protocol for the administration of radioactive substances.

These changes would normally meet the criteria for notifying substantial amendments to the Research Ethics Committee (see SOP C105 on Amendments)

2.10 To submit an amendment to ARSAC, the CRIO Coordinator or delegate should create an amendment to the Research Application on the ARSAC online Portal, at the same time as submitting the amendment tool to IRAS

2.11 The CRIO Coordinator or delegate should complete all the required questions and attach the following;

a) Amendment tool
b) Updated PRA or New PRA Form because there may be changes to the number of administrations or procedures involving radioactive substances (see 2.1 on how to do this).
c) Any other relevant documentation such as PIS.

2.12 Once the study has been approved an approval document will be added to the portal to download, while ARSAC assesses the amendment, the study remains authorised within the limits of the initial approval and administrations may continue in line with this.

2.13 Applications to ARSAC, new and amendments will be charged; once amendments have been submitted ARSAC will contact the applicant on when and how to pay. The CRIO coordinator should ensure there is funding for all applications to ARSAC, including any amendments.

2.14 ARSAC should also be notified of minor changes to trials such as changes to a research title or closure of a trial; notifications should be made to the ARSAC Support Unit by email to ARSAC@phe.gov.uk. These notifications are not subject to any fee.

2.15 The CRIO Coordinator downloads the ARSAC Certificate from the ARSAC on-line portal and saves this under section 3.1 in RMS, alongside REC and HRA approval.

2.16 The CRIO Coordinator approves the appropriate tab in RMS for ARSAC approval. Note that the overall MIMP task will not be approved until evidence of the ARSAC approval has been uploaded to RMS and checked by MIMP staff that all trial procedures are covered by existing licences.

3. Participating Site MPE/CRE Assessment, Cost and Capacity requests for MIMP procedures

3.1. Principal Investigator, Study Coordinator, or CRIO Coordinator describe all ionising radiation exposures that could be performed at STH in the course of a research project on the current

version of the MIMP form. The exposures considered SOC and those additional at STH must be identified. Other imaging procedures that do not involve radiation need to be included on the MIMP form e.g. MRI and Ultrasound. Even where a research project may result in less ionising radiation exposures, compared to SOC for a patient, all exposures must be recorded on the MIMP form and assessed by competent MPE(s) and CRE.

3.2. Principal Investigator or Study Coordinator completes the MIMP form and submits it to the CRIO Coordinator.

3.3. CRIO Coordinator uploads the completed MIMP form together with a Protocol, Participant Information Sheet (PIS), IRAS Form, and Imaging Manual (if available) to the appropriate section within Alfresco under the STH study number.

3.4. CRIO Coordinator ensures the required documents are saved in the appropriate sections within Alfresco whilst ensuring that MIMP access is enabled within RMS so that they can be retrieved by the MIMP Coordinators for their review.

3.5. The CRIO Coordinator should start the MIMP task in RMS. Where the MPE/CRE has fallen outside of MIMP, the CRIO Coordinator creates a separate task in RMS for IR(ME)R compliance.

3.6. If the protocol requires a Nuclear Medicine procedure the ARSAC Research Approval from the Sponsor should be requested by the CRIO Coordinator and uploaded to the MIMP section in RMS.

3.7. The MIMP coordinators will review the study documents and may reject on RMS at this early stage if the documents do not correspond e.g. the number of imaging procedures or treatments differ between documents or if all the required documents have not been provided.

3.8. MIMP Coordinators will inform the applicant if MIMP staff are not competent to review all radiation exposures in a protocol and may provide information on who else in STH may also need to provide an assessment of the ionising radiation that MIMP staff are not competent to review.

3.9. MIMP Coordinators will identify procedures that can be assessed for IR(ME)R compliance by MIMP staff but that are not provided as a service by MIMP (for example: PET/CT, DXA/HR-pQCT, Radiotherapy and vascular or cardio radiology).

3.10. For those services not provided by MIMP (PET/CT, DXA/HR-pQCT, Radiotherapy and some Radiology), the CRIO or Directorate Coordinator should contact those providers at this stage. For such studies, where the MPE/CRE has fallen outside of MIMP, the CRIO Coordinator creates the necessary task in RMS for IR(ME)R compliance.

3.11. MIMP Coordinators will provide the costs for MIMP administration and activity in the research project to the Principal Investigator, Study Coordinator or CRIO Coordinator. This may include costs for non-standard reporting of images, submission of images for central review, for new reporting measurement criteria not currently used a 3D Lab set up cost will apply.

3.12. The MPE(s) and CRE will provide an opinion as to whether IR(ME)R and ARSAC compliance can be demonstrated. Additional information may be requested from the PI or the Co-ordinators to facilitate this decision. A summary of this assessment will be recorded on RMS.

3.13. If the procedures are not covered by an existing ARSAC certificate or licence then the MPE/CRE will advise the MIMP Co-ordinators of this and whether or not there will be an application charge to be paid to add the procedure(s) to the certificate or licence. It is likely that the MIMP Co-ordinators will co-ordinate the required application to ARSAC and sign off will be required by the relevant MPE(s) and Practitioner(s). If a novel radiopharmaceutical is to be used, which is not covered by the existing Trust environmental permits, a variation to change the permit will need to be submitted to the Environment Agency. The variation can take up to 3 months to process once the payment has been made to the Environment Agency so the application needs to be submitted as a priority. Funding to cover the application fee is likely to be required as part of set up costs and is currently in region of £7200 for each hospital site where the exposure will be performed.

3.14. MIMP Co-ordinators will organise the electronic sign off on RMS by the competent MPE/CRE. The appropriate documents confirming approval will be uploaded to Alfresco. The R&D Coordinator organises the electronic sign off on RMS by the competent MPE/CRE for studies that fall outside of MIMP for IR(ME)R compliance.

3.15. If the MPE are CRE do not feel that the documentation satisfies the requirements of IR(ME)R and are unable to give local approval they will reject the study on RMS and further information will be requested from the study team or sponsor.

4. Procedure for assessing IR(ME)R Compliance where a protocol requires radiotherapy

Note: Radiotherapy Physics is a separate Directorate to MIMP.

For exposures involving Radiotherapy, the CRIO Coordinator liaises with the Head of Radiotherapy Physics (HoRTP) or appropriately delegated MPE for Radiotherapy.

A Consultant Clinical Oncologist (CCO) (radiotherapy specialist) acting as Local Practitioner (LP) must determine clinically whether the trial radiotherapy is acceptable. This will take into account the radiobiological effect of the dose and fractionation proposed combined with imaging doses arising from the protocol. The Cancer Clinical Trials Executive (CCTE) form will indicate whether the local PI is a CCO and can therefore act as LP and if not, will indicate a named CCO who may act as LP. For studies that fall outside of Cancer Clinical Trial Centre review or for clinical trials involving standard care radiotherapy the local PI may not be a CCO, Clinical input into determining that the trial radiotherapy is acceptable will be sought from a CCO, acting as LP. The HoRTP will be able to identify a suitable LP. For studies involving the Gamma Knife facility (aka National Centre for Stereotactic Radiosurgery) which is a separate division to Radiotherapy Physics, Lee Walton should act as MPE. This will be in addition to the HoRTP's MPE approval where studies include WPH radiotherapy.

It is imperative that any trials involving any form of Radiotherapy, including exposures described in the Protocol which are 'standard of care' at STH, are notified to the CRIO Coordinator at the earliest opportunity by PI to initiate this process.

Determination of the total radiation dose in a trial, because of the clinical condition of the patients involved, does not need to be reported, therefore the separate confirmations of STH compliance with IR(ME)R described in this section is satisfactory.

Procedure

4.1. The CRIO Coordinator is notified of trial Radiotherapy by either review of the CCTE Form, or email notification by PI or study team.

4.2. The CRIO Coordinator reviews the CCTE Form or email to establish if the PI is a CCO and can act as LP.

4.3. If the PI is not a CCO, the CRIO coordinator will contact the HoRTP to seek advice on who should act as LP for the study in question.

4.4. For studies involving Stereotactic Radiosurgery, the MPE is a named contact at the Gamma Knife facility and they should be contacted for the following steps involving MPE review.

4.5. Once the LP is established, the CRIO coordinator provides LP with the Protocol, IRAS Form, PIS and any other required documents in an email along with the statements below which they are required to comment on.

4.6. The LP is required to advise if STH can adhere to the clinical aspects of the Protocol and the following statement should be emailed to them asking them if;

a) The radiotherapy doses in the protocol (including associated verification images) are normal practice at STH, or;

b) Where local patients would receive a dose different to normal practice at STH, that:

i. this has been identified in the IRAS form and has been ethically approved by the REC, and that;

ii. any 'additional exposure' is justified with an acceptable balance for efficacy vs toxicity and having regard to IR(ME)R.

iii. That the risk associated with the change in radiotherapy treatment is adequately described in the PIS.

4.7. The CRIO Coordinator starts a task in RMS indicating LP review has begun.

4.8. In addition to LP review, the HoRTP (or delegate) acting as MPE must review the radiotherapy doses in a trial and determine whether the radiotherapy is technically achievable and has the capability to deliver the doses and techniques required. The MPE may also be required to support the LP in evaluating radiation doses arising from applying the trial protocol locally. The CRIO Coordinator records an email approval summarising this assessment on RMS.

4.9. The CRIO Coordinator starts a task in RMS indicating MPE for Radiotherapy review has begun.
4.10. Upon receipt of satisfactory approval form the LP and MPE the CRIO Coordinator completes the tasks in RMS for accordingly.

In the temporary absence of HoRTP, the Lead Clinician for Radiotherapy, will co-ordinate the response of the Clinical Oncologists (local practitioner) and approach a Principal Physicist to act as MPE to allow a preliminary decision to be made about capability. This should be forwarded to the HoRTP on their return from absence.

5. Procedure for assessing approval from service providers that do not fall under MIMP Coordination

For studies requiring Dental X-Rays, PET/CT, DXA and HR-pQCT scans the following procedure must be followed to ensure the service provider is aware of the study and they can confirm capacity and capability to carry out the tasks. All activity must be listed on the MIMP Research Approval Form for IR(ME)R Compliance which the MIMP Coordinators will seek MPE review for, but this additional procedure is for costing and approval for the activity itself with the provider. This would serve as confirmation from the service provider that the activity required in the Protocol can be delivered but it should be noted that overall approval will be complete when MIMP have approved the task in RMS to confirm MPE and CRE approval has been obtained. Appendix 2 lists the persons who is the contact at the site and the following procedure should be carried out to gain their approval.

5.1. Where activity is identified as those listed above, the CRIO Coordinator contacts the service provider via email and provides them with a copy of the completed MIMP Research Approval Form, IRAS Form, Protocol, and PIS for review.
5.2. CRIO Coordinator starts a task for this review by dragging over an ‘Other support service’ task folder and places it under the ‘Support Service’ section under the Tasks tab in RMS.
5.3. CRIO Coordinator starts this task and labels this manually with reference to the appropriate service provider for examples ‘AML PET CT’ or ‘NGH DXA/HR-pQCT’, adds the appropriate contact person.
5.4. There may be a requirement for the CRIO Coordinator to liaise with the Sponsor or study team to address any questions arising from the service provider’s review.
5.5. If acceptable to the service provider, they will provide the CRIO Contact with a price per scan which is calculated a total cost per patient for the whole trial. This will be via an email.
5.6. Once confirmation of capability is received, the CRIO Coordinator files the email in Section 8.6 of Alfresco and approves the task, noting that approval is on the basis of overall MIMP approval for IR(ME)R compliance and/or ARSAC Certification if required.

Appendix 1 - Associated Documents

	Document	S-drive	Website	Database	Who
1	MIMP Form	S:\General\Research Governance\Project Authorisation\Templates\RD templates\MIMP Research Approval Form Vers 8.doc	Yes	No	MIMP

Appendix 2 Current Specified Contacts

MIMP Coordinators	Sally Fleming, Bridget Billingham (sally.fleming1@nhs.net and bridget.billingham@nhs.net).
Cath Lab	CRIO Research Coordinator for SYR
HoRTP	Dr Steven Tozer-Loft stephen.tozer-loft@nhs.net
Lead Clinician for Radiotherapy	Dr Simon Pledge simon.pledge@nhs.net
Principal Physicist	Dr Steven Young steven.young4@nhs.net
MPE Delegate at Gamma Knife Facility	Mrs Katie Hunt katharine.hunt@nhs.net gamma.knife@nhs.net
Alliance Medical Limited (AML)	Pedro Goncalves PGoncalves@alliance.co.uk
DXA/HR-pQCT Scan requests	Dr Margaret Paggiosi M.A.Paggiosi@sheffield.ac.uk
Dental X-Ray	Emma Bird e.v.bird@sheffield.ac.uk
University of Sheffield PET MRI scanner	Prof Jim Wild j.m.wild@sheffield.ac.uk for TUoS & Phil Hillel philip.hillel@nhs.net at STH