PET research set-up guide

Please refer to this guide if you wish to set up a research study involving PET-CT (including Total Body PET) or PET-MR from the PET Centre

The **PET Research Delivery Coordinator (RDC)** will be your main point-of-contact, who will guide you through the process and confirm what steps are required to set up your research at the PET Centre.

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Stage 1: Application

All research study involving PET-CT or PET-MR will need to be reviewed by the PET Research Review Committee.
Please see the following steps required at the application stage.

Steps	Information
Submit proposal form *[The proposal form is available on the **PET Centre website** or can be requested from the RDC]*	Complete and submit the preliminary proposal form to the Research Delivery Coordinator (RDC) - **Sheut-Ling.1.Lam@kcl.ac.uk** You are strongly encouraged to discuss your proposal informally with the relevant members of the PET Centre before completing the form. If you need assistance, please contact the RDC. Kindly ensure that your forms are submitted at least one week* before the next monthly PET Research Review meeting, allowing enough time for distribution to committee members for review. Depending on the nature of your study, you may be invited to attend the meeting to present your proposal. *Please note that during busy months, when we receive a high volume of applications, your proposal may be discussed at the following meeting instead. The RDC will confirm the date once your proposal form is received.
Study reviewed at the PET Research Review Meeting	Attended by the various stakeholders and experts associated with the PET facility. The proposal will be reviewed with respect to scientific and technical aspects, and the resources and funding required to support it. A decision on whether to support the study in principle will be made. The RDC will inform you of the decision and will confirm the next steps.

Stage 2: Study Set-Up

This stage begins after receiving formal confirmation of support from the PET Research Review Committee of your study.
The RDC will confirm the steps (marked 'X') from the following checklist that you need to complete to get your study set up at the PET Centre.

Step	Information	Required (X)
Clinical Scientist study allocation	One of our Clinical Scientists (Medical Physicist) will be assigned to your study; they will co-ordinate and be the main point of contact for all technical aspects of your study and data analysis as agreed. For PET-MR studies the PI/researcher will specify to the PET-MR Superintendent the MR sequences required. The scanning protocol will be set-up by the PET-MR Superintendent and the Clinical Scientist assigned to the study. Expert help will be sought form an MR physicist when required. The clinical scientist will also facilitate obtaining any new Risk Assessments or associated permissions required by the study protocol (e.g., use of unusual radionuclides etc)	
Set-up Meetings	A series of set-up meetings with the researcher/PI, the assigned clinical scientist and other members of the PET team will be organised to ensure that all technical requirements for the study are in place and/or routes to obtaining them if not. In some cases, this process may take a considerable time depending on the complexity of the project. The Clinical Scientist will oversee the backup and transfer of scan data as agreed and equipment are in place. When setup is nearing completion, patient scheduling, and booking arrangements can be made. Scan booking slots are to be coordinated with the Chief PET Technologist.	
Costings approval	It is important that study costs are discussed and reviewed by the PET Service Manager at this stage. Costs are calculated for tracer production/development and scan time/length, and if applicable arterial line insertion, blood sampling, and metabolite and data analysis requirements. Details of funding status/source for the radiotracer provision and/or radiotracer development should be provided to the PERL Operations Manager.	

Study Registration (R&D) and Sponsorship	You will need to register your study with your local R&D department (or Clinical Trials Office for CTIMP studies), who will assist in the regulatory (e.g., Health Research Authority (HRA), NHS Research Ethics Committee (REC) etc.) **IRAS** submission process and confirm sponsorship arrangements. • **Guy's and St Thomas' (GSTT) Patients:** If your study involves scanning GSTT patients, you will need GSTT R&D approval and/or co-sponsorship. • **Non-GSTT patients:** If your study involves scanning of non-GSTT patients only, you may still require confirmation of capacity and capability from GSTT R&D to host your study. Please note that if patients referred to the PET Centre for your research are recruited from non-KHP sites only, a Service Level Agreement (SLA) may be required between KCL (the PET Centre) and the referring institution(s).	
In-house Radiotracer supply (from PERL)	Radiotracer supply – If the radiotracer is to be supplied from PERL, contact the PERL Operations Manager to verify if the radiotracer is available from the PERL tracer portfolio and to assess whether the production schedule will allow sufficient provision of the requested radiotracer. If a new/novel radiotracer is required, a radiotracer request form should be obtained, completed and returned to the PERL Operations Manager. The PERL team/Operations Manager will conduct a feasibility assessment and provide the PI with an estimated timescale for conducting the radiotracer development/validation. Typically, a period of 9-12 months should be allowed for the development/validation of a new radiotracer. During the development phase, the PI may be contacted to engage in further discussions such as determining radiotracer product specifications.	
Radiation Assurance - IRAS (Integrated Research Application System**) form**	For the IRAS Part B (section 3) radiation specific parts of the IRAS form (A1-D4): • **Radiation Dose and Risk Assessment reports:** To be completed in IRAS by a qualified **Medical Physics Expert (MPE)** and a **Clinical Radiation Expert (CRE)** and electronically signed off prior to IRAS submission. For KCL/GSTT sponsored studies, the MPE and CRE will usually be assigned from PET Centre staff. • **The ARSAC Preliminary Research Application (PRA):** This is automatically populated from the fully authorised main IRAS form and can be submitted in parallel with the HRA/REC submission via the ARSAC online portal, along with the PIS. Create a New Research Application on the ARSAC online portal at the same time as you submit to the HRA/REC. Ensure that the patient risk described in the PIS aligns with the MPE assessment in the PRA and follows HRA's recommended wording. Submission of ARSAC PRA will require a cost – refer to **ARSAC website** for details.	

ARSAC practitioner and employer licence	An ARSAC practitioner must be assigned to the study. For KCL/GSTT sponsored studies, the ARSAC Practitioner will usually be a member of PET Centre staff. If the radiotracer you plan to use and its indication are not listed on the current ARSAC GSTT employer licences or the PET clinician's practitioner licence, an ARSAC amendment must be submitted to include the tracers on the licence(s). The RDC will assist with this process, but please be aware that it can take 6–8 weeks and will incur a cost from ARSAC.	
IRAS Submission	You can submit your IRAS form when this has been fully completed, electronically authorised and your R&D office has reviewed and given their approval. You will also need to book/submit the following: • **Book REC review meeting:** this can be booked via the **online booking service** using the 'e-submission' tab on IRAS. • **Submit ARSAC PRA and PIS:** Submit the ARSAC PRA and PIS to the ARSAC online portal for review. There is a charge from Public Health England for the ARSAC review - refer to **ARSAC website** for details.	
Non-CE marked/off-label/in-house developed equipment or software	If PET aspects of the project are to use any non-CE marked equipment or software, or CE marked equipment or software that will be used off-label, or in-house developed equipment or software, then approval may be required for the use of these. Please consult with the Clinical Scientist for advice.	
Regulatory approvals	Once all necessary regulatory approvals are in place, ensure that all copies of the approvals and approved study documents are sent to RDC and your local R&D office. Please note that ARSAC approval for your research is valid only if both the employer and practitioner's ARSAC licence lists the approved radiotracer to be used for your research at the PET Centre. R&D will check you have all the necessary approvals in place and will liaise with the PET centre to re-confirm we are able to support the study before they grant final approval for the study to start. Information on the status of ARSAC/Ethics approval for the study should be provided to the PERL Operations Manager.	

King's Health Partners (KHP) Passports	KHP passports are required for any non-GSTT employed researchers involved in carrying out a study on GSTT premises. Please provide these to the Clinical Scientist/RDC who can ensure they are signed off by the appropriate GSTT person. If researchers are from an institution **not** affiliated with KHP they may need a GSTT honorary contract which can be arranged by the GSTT HR department, and there may be charge for obtaining this.	
PET Centre Training	Researchers/nurses accessing the PET centre's radiation-controlled areas must attend a basic radiation safety presentation and read and sign our local site rules. Training is provided by our physicists here on site. We encourage referrers to attend the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) training offered by GSTT. Researchers accessing the PET-MR scanning suite will need to attend **KHP** MR safety training or provide evidence to the PET MR Superintendent. The latter will also provide a PET-MR induction and emergency evacuation session. Please note we do not accept evidence of MR safety training performed elsewhere.	
Arterial lines and blood sampling	For studies involving arterial lines, the PET team will need to assess the availability of a trained clinician to cannulate the patient. Aftercare of the line and blood sampling will need to be performed by a member of the PI/researcher's team who should be a clinician (unless specifically agreed otherwise). Training on arterial line maintenance can be provided. If metabolite analysis is needed, this will require specific expertise and resources, the PET Centre will support you with this.	
Referral and consent	For each research scan a patient referral form should be completed (if no possible via EPIC) and signed by the referring clinician and a copy of the signed patient consent form must be available in the PET Centre prior to the scan. No research study will take place without the relevant signed consent form.	
Tracer failure and delays	Ordering of radiotracer and booking of scan slots is arranged via a senior designated PET radiographer: • For PET-MR studies – Coordinated with the PET-MR Superintendent • For PET-CT studies – Coordinated with the PET-CT Superintendent The scanner time available and dates of tracer availability will vary depending on the study and can change throughout the course of the trial. Regular pre-booked slots and tracer supply should be negotiated with our	

	radiographers and tracer supply team (in-house or external) prior to commencing the study. Pre-booked scanner slots should be re-confirmed and patient referral details received 5 working days in advance to release unused slots and maximise scan time available to other research teams and clinical patients.		
Scan Review and incidental findings	For PET-CT and PET-MR research scans it is the responsibility of the researcher to ensure that arrangements are in place for the scan to be formally reviewed/reported by an appropriately qualified clinician in case of incidental or unexpected findings (unless participants have been specifically informed in an REC approved consent form that images will not be reviewed by a clinical expert). Researchers are strongly encouraged to fund and arrange scan review by an appropriate clinician. Standard clinical reporting pathways will not apply to research scans and research scans will not automatically be reviewed or reported by a PET centre clinician. In the case of an unexpected abnormality being noticed by our clinical staff during or after the scan which is judged to require urgent medical attention or intervention; our local incidental findings policy will apply in consultation with the researcher's team.		

Stage 3: Greenlight to start

When all the necessary steps from the Stage 2 (set-up) checklist are completed, you will receive the formal approval/greenlight from the RDC to confirm that scanning can commence for your research (for prospective acquisition) or approval for retrospective imaging access for your research.

Contacts and resources:

PET Centre: http://www.sthpetcentre.org.uk/

- General email: gst-tr.PETCentre@nhs.net
- PET Research Delivery Coordinator (RDC): Sheut-Ling.1.Lam@kcl.ac.uk
- Clinical and Research PET Service Manager: Giorgio.Testanera@kcl.ac.uk
- Head of PET Imaging Centre & Professor of Imaging and Neuroscience: Alexander.Hammers@kcl.ac.uk
- Professor of PET Physics (Chair of PET Research Review Committee): Paul.Marsden@kcl.ac.uk

PERL contact mailbox: perl@kcl.ac.uk

GSTT R&D Office: https://www.guysandstthomas.nhs.uk/research/research-and-development/research-partnerships

ARSAC application guide: https://www.guysandstthomas.nhs.uk/research/research-and-development/research-partnerships

IRAS online guide: https://www.myresearchproject.org.uk/ELearning/IRAS_E_learning.htm