How to set up a research study involving PET-CT or PET-MR

1. **PI/Researcher submits new Project Proposal Form to the PET Research Co-ordinator (Emma Sperring)**
   The research coordinator is the main point of contact for all prospective general study set-up queries and advice on regulatory and submission processes. Approach the research co-ordinator as soon as possible as we cannot guarantee to support projects which have not been discussed in advance or costed formally. If a novel or non-routine tracer is required from our Positron Emitting Radiotracer Laboratory (PERL), contact information for discussion with our chemistry team can be provided.

2. **Study discussed at monthly PET Research Committee Meeting**
   Attended by senior staff members representing various teams in PET. A decision on whether to support the study in principle will be made. Any questions raised will be forwarded to the researcher following the meeting.

3. **Researcher to contact Pallavi Patel (Service manager) to agree formal study costs**
   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.

4. **A PET centre Clinical Scientist (Medical Physicist) is assigned to project**
   They will co-ordinate and be the main point of contact for all technical aspects of the study and data analysis as agreed. This will also include data transfer and back up of study data. For PET-MR studies the PI/researcher should advise on specific MR sequences required. For novel MR sequences that have not previously been set up an MR physicist will be available for input on sequence development.

5. **PI/Researcher develops study Protocol documents, PIS and IRAS forms online (in consultation with R&D)**
   Any prospective study should be registered and sponsorship arrangements agreed with your local R&D department (or Clinical Trials Office for commercial or CTIMP studies) who will assist in the HRA/REC submission process. For patients recruited at GSTT, GSTT R&D approval/co-sponsorship is required (involving a review of capacity and funding). For non-GSTT patient studies in PET, GSTT R&D should be informed to confirm basic capacity. For non KHP patients a Service level agreement (SLA) contract may need to be in place between KCL (PET centre) and the referring institution.

6. **Radiation Assurance - for the IRAS Part B (section 3) radiation specific parts of the IRAS form (A1-D4)**
   Radiation Dose and Risk Assessment reports must be generated and electronically signed in IRAS by a qualified **Medical Physics Expert (MPE)** and a **Clinical Radiation Expert (CRE).** A list of HRA approved MPE's and CRE's are available via the HRA radiation assurance website. You should complete a Radiation Assurance Research Exposure Form (F1) for the HRA who will then allocate an MPE and CRE to review and generate dose reports for the IRAS and electronically sign off your IRAS form.* There may be charges for this service. Any subsequent radiation dose changes must be reviewed and re-authorised by the MPE and CRE. The ARSAC Preliminary Research Application (PRA) is automatically populated from the fully authorised main IRAS form and can be submitted to ARSAC in parallel with REC submission. **Check with the PET research co-ordinator if the radiotracer you want to use is included on the current ARSAC GSTT employer license and PET practitioner license. If novel, it may need to be added.**

7. **IRAS forms, Protocol, PIS and study documents are complete and authorised and can be submitted.**
   When the IRAS forms have been electronically authorised and R&D have approved capacity you can submit to the Health Research Authority (HRA)/Research Ethics Committee (REC), book your REC committee review

meeting and submit the PRA form by email to ARSAC for review. There is a charge from Public Health England for the ARSAC review of £300 which is to be paid by credit card. (£250 for subsequent amendments).

8. **Approvals received from REC/HRA, ARSAC and lastly, R&D department**
   After REC and HRA approval is granted and the ARSAC PRA form doses are approved in principle by ARSAC, inform the PET research coordinator. ARSAC approval for the study will only apply if the institution administering the tracer holds an ARSAC employers license which lists that tracer. Similarly an ARSAC approved Clinician at that institution also needs to hold a practitioners license listing that tracer. The tracer will be administered under their responsibility. Copies of all documents and confirmation of this should also be sent to local R&D. R&D will check you have all the necessary approvals in place and will then grant final approval for the study to start.

9. **'Start-up Meeting' with the Researcher/PI and PET team will be organised.**
   The scanning protocol document and patient scheduling and booking arrangements will be finalised and the scanning protocol set up on scanner with input from the PET team. The Clinical Scientist will ensure backup and transfer of scan data as agreed, and any blood sampling arrangements and equipment is set up. Study specific training may be required depending on the researcher role as detailed below. The study can now start.

*The Radiation Assurance process is not yet mandatory but will shortly become mandatory. Liaise with the PET research coordinator for advice on the best route for your study. You can request Radiation Assurance via the HRA 'Self managed route' and request a specific MPE/CRE (known to you) but they should be HRA registered and employed by the study sponsor organisation.

PLEASE NOTE: PET CENTRE RULES

1) **King's Health Partners (KHP) Passports**
   KHP passports are required for any non-GSTT researchers involved in carrying out a study on GSTT premises. Please provide these to the Clinical Scientist/Research Coordinator who can ensure they are signed off by a GSTT clinician. If researchers are from an institution not affiliated with KHP they may need a GSTT honorary contract which can be arranged by GSTT HR. There is a £350 charge for obtaining this.

2) **Training**
   Researchers/Research Assistants/nurses will need to attend radiation safety training and read PET centre local rules. This training is provided by our physicists here on site. Specific Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) training for referrers is provided by GSTT and attending this course is encouraged.

   Researchers accessing the PET-MR scanning suite will need to attend KHP MR safety training or provide evidence that appropriate training has been completed elsewhere.

3) **Tracer failure and delays**
   Researchers must be always be present during patient scans (unless specifically agreed) and must take responsibility for their patients, including explaining and dealing with issues related to tracer delays/failures. For scans cancelled/aborted at short notice by the researcher and where tracer or scanner time costs have been incurred by the PET centre, costs may be charged to the PI/researcher.

4) Arterial lines and blood sampling

For studies involving arterial lines a trained clinician will be provided by PET 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 will be provided.

5) Referral and consent

For each scan a patient referral should be made and a copy of the signed consent form must be available in the PET Centre prior to the scan. No research study will take place without the relevant consent form.

6) Tracer ordering

Ordering of radiotracer and booking of scan slots is arranged by a senior designated PET radiographer. For PET-MR studies – Senior PET-MR radiographer. For PET-CT studies – Senior PET-CT radiographer.

7) Scan review/reporting 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 reviewed/reported by an appropriately qualified clinician in case of incidental or unexpected findings (unless explicitly agreed by ethics that review of the scan is not required). Researchers are strongly encouraged to fund and arrange scan review. 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.