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. Ideally the research coordinator should be approached prior to receiving any grant funding as we cannot guarantee to support projects which have not been discussed in advance or costed formally.

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**
   Cost are calculated for tracer production/development and scan time/length, arterial line insertion, blood sampling, and metabolite and data analysis requirements.

4. **A PET centre Clinical Scientist (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**
   Input from PET Clinical Scientist/Research coordinator. For the Part B (section 3) radiation specific parts of the IRAS form (A1-D4) **DO NOT TRY TO COMPLETE THIS PART OF THE IRAS FORM. THE PET CENTRE WILL DO THIS.** A Radiation dose report and a Clinical Risk Assessment must be completed and electronically authorised by a qualified PET Centre **Medical Physics Expert (MPE)** and **Clinical Radiation Expert (CRE).** The research coordinator will advise on who these will be for your project. Any subsequent protocol/PIS amendments that relate to PET part of study must be reviewed and re-authorised by the MPE and CRE. The ARSAC PRA and RCA forms are automatically generated and populated from the fully authorised main IRAS form.

6. **Researcher registers project with local R&D department and submits draft IRAS form to them for review.**
   For patients recruited at GSTT, GSTT R&D approval is required (involving a review of capacity/funding). For patients recruited at IoPPN, SLaM R&D approval is required. When R&D has agreed sponsorship arrangements and approved the IRAS form you can submit to HRA/REC. For non GSTT patient studies in PET, GSTT R&D should be informed to confirm basic capacity. For non SLaM/GSTT patients a Service level agreement (SLA) contract may need to be in place between KCL (PET centre) and referring institution.

7. **Researcher submits fully authorised IRAS form electronically to HRA/REC, and arranges REC committee meeting. Researcher submits IRAS PRA form via email to ARSAC**
   After REC approval is granted and the ARSAC PRA form is approved in principle by ARSAC, inform the PET research coordinator. The site specific ARSAC RCA paperwork and hard copy documents can now be submitted by the research co-ordinator, who will notify you when the ARSAC approval certificate is received. Copies of all documents should also be sent to local R&D.

8. **Final R&D approval received.**
   R&D will check you have all the necessary approvals and funding and will then grant final approval

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 Clinical scientist/PET radiographers/MR physics. 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.

10. Study starts!!!!

PLEASE NOTE:

1) **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.

2) **Training**
   Researchers/RA's/nurses will need to attend radiation safety training and read PET centre local rules etc. This training is provided by our physicists here on site. Specific IRmer training for referrers is provided by GSTT and attending this course is encouraged.

   Researchers accessing the PET-MR scanning suite will need to attend GSTT 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 partient. Aftercare of the line and blood sampling will need to be performed by the PI/researchers team and should be a clinician (unless specifically agreed). 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 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-MR studies and research scans involving novel tracers 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 agreed by ethics that review of the scan is not required). 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.