STEPS IN LAUNCHING A STUDY

**Actions for Principal Investigator (PI)**

- PI contacts CIVI (civi@newcastle.ac.uk) with study expression of interest.
- If project requires NRES approval - must discuss the project with MR Physics team prior to making application for ethical approval.
- **PET studies** are complex - requires discussion with the PET scientific/technical team at the earliest opportunity.
- **Radioactive tracer** – PTPU unit could produce tracer. PI to inform CIVI of this requirement at the expression of interest so that PTPU can be consulted.
- PI completes costsings request form and returns it to CIVI.

**Actions for CIVI**

- CIVI liaise with Study Team (Radiographers, Physicists, Clinical Scientists, PTPU & Unit Directors) to ascertain study feasibility.
- If required, CIVI contacts PI to arrange a meeting to discuss: study, technical evaluation, resources, opportunities for collaboration scientific input, and for PET studies advice for ARSAC application and/or radioactive tracer.
- If feasible, costsings request form sent to PI.
- CIVI populate applicable charges on the costsings request form; circulates to Study Team for final review and sign-off by Unit Director. If required, PTPU consulted for tracer costing.
- Finalised signed costsings form and costsings approval supporting documentation sent to PI.

**Study accepted internally**

- PI updates CIVI at time of funding.

**Prior to Ethics submission**

- PI sends Ethics application and Patient Information Sheet to CIVI. PI to consult with MR Clinical and Physics team.

**Pre-Registration**

- Once all approvals are in place, PI provides:
  - Protocol, Patient Information Sheet(s) and Consent(s)
  - Favourable Ethics notification
  - HRA, R&D approvals
  - ARSAC verification (PET ONLY)

- PI completes study registration form.
### STEPS IN LAUNCHING A STUDY

<table>
<thead>
<tr>
<th>Study registered and Study Number issued</th>
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<tr>
<td>PI sends delegation log to CIVI</td>
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<tr>
<td>PI contacts Radiographers to book scans</td>
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<tr>
<td>PI and/or study staff attend for tour, magnet safety briefing and/or clinical safety briefing, if applicable</td>
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- PI provided with registration pack
- CIVI obtain signatories. Returns log to PI