Telephone: 0191 208 1250, Fax: 0191 208 1151

Email CIVI@ncl.ac.uk, www.ncl.ac.uk/civi



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 <u>NRES approval</u> - must discuss the project with MR Physics team prior to making application for ethical approval.

<u>PET studies</u> 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

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.

PI completes costings request form and returns it to CIVI

If feasible, costings request form sent to PI

CIVI populate applicable charges on the costings request form; circulates to Study Team for final review and sign-off by Unit Director. If required, PTPU consulted for tracer costing.

Finalised signed costings form and costings 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.



Clinical and Physics staff review Ethics application and Patient Information Sheet.

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

Study registration form sent to PI

working together as Newcastle Academic Health Partners



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STEPS IN LAUNCHING A STUDY

Study registered and Study Number issued

PI sends delegation log to CIVI

PI provided with registration pack
CIVI obtain signatories. Returns log to PI

PI contacts Radiographers to book scans

PI and/or study staff attend for tour, magnet safety briefing and/or clinical safety briefing, if applicable



