Registering the project (before data collection):

This document is designed to assist local investigators set up the project at their local hospital or trust, with support from their regional trainee network iHypE lead.

Identifying local 'trainee leads', data collectors and a supportive consultant. The responsibilities of the local trainee leads are to:
1. Provide leadership for the study in their institution.
2. Enrol a supportive consultant supervisor. This is <u>mandatory</u> for support and governance. The consultant will have to act as the local 'principal investigator' as they are full time employees of the trust (as opposed to trainees). Please note that even if the trainee lead is in a non-training post, a consultant supervisor will still be required at the site.
3. Register the study with your Research & Development (R&D) Department, ensuring this process is completed by <u>Monday 14/11/16</u>.
4. Ensure that there are sufficient data collectors to cover all recovery/ PACU's on the days of the study if the hospital has more than one.
5. Collect data and act as guarantors of data quality and integrity.
6. Communicate with your local trainee network co-ordinator.

Regulatory approvals with your R&D department must be in place prior to data collection. The joint roles of the local trainee lead and consultant supervisor are to:

	Task	**Complete**
A	Contact the R&D Department at your hospital stating you wish to take part in iHypE. A template e-mail is provided at the bottom of this document. To find your local R&D contact details, you can ask your supporting consultant, use the hospital switchboard or intranet or look on http://www.rdforum.nhs.uk/content/contact-details/ The relevant code numbers for the project are: a. Integrated Research Applications Service (IRAS) 186097 b. Central Portfolio Management System (CPMS) 31771 (www.ukctg.nihr.ac.uk) c. UCL Study Reference 15/0970 d. International Standard Randomised Controlled Trial Number (ISRCTN) - tbc Documents to support your registration can be obtained from your network trainee lead.	
B	Inform your Anaesthetic Department Lead Clinician by e-mail.	
C	Complete Good Clinical Practice Training. See *'NIHR Good Clinical Practice Training Registration'* for more information.	
D	Complete the UCL Data Processing Agreement (RAFT iHypE - UCL Data Processing Agreement v 2 6.7.16). This should be completed by the local team in conjunction with the R&D department.	
E	Send confirmation of successful registration with your R&D department to: a. info@i-hype.org b. Cameron.berg@uclh.nhs.uk (UCL Joint Research Office study representative)	

O b s e r v a t i o n a l   S t u d y   o f   I n t r a o p e r a t i v e
H y p o t e n s i o n   i n   E l d e r   P a t i e n t s   i n   U K
H o s p i t a l s   (i H y p E)

	c. Your local trainee network iHypE lead Please attach the following documents to this e-mail: a. A completed HRA Statement of Activities form (document "RAFT iHypE - HRA - Statement of Activities"). This will be completed by the local R&D department. b. A completed and signed Data Processing Agreement (document "RAFT iHypE - UCL Data Processing Agreement v 2 6.7.16").	
F	<u>Once you have completed items A-F:</u> Register your site with Anaesthesia Audit (the address will be provided prior to the study going live). Each data collector must register. Note you will need to use an NHS e-mail address to register (Gmail, Hotmail & Doctors.net are not recognised). You will receive an email containing: a. Your unique investigator number which will be required when entering data on REDCap. b. Links to the REDCap data entry portal.	

Template e-mail to Research & Development Department
Attach the documents provided to you by your regional representative

To:	*Find your local R&D department contact details from the hospital intranet, switchboard or ask your supporting consultant.*
CC:	Regional research network trainee lead
Subject:	Anaesthetic study – RAFT iHypE
Text:	Dear R&D team, **Re: Intraoperative Hypotension in Elder Patients (iHypE): An Observational Study of Intraoperative Hypotension in patients aged over 65 in UK Hospitals** We would like to participate in an anaesthetic trainee led observational research study on intraoperative hypotension in elderly patients having surgery. The study is sponsored by University College London, funded by the National Institute of Academic Anaesthesia and is NIHR portfolio registered. The relevant registration numbers are: • Integrated Research Applications Service (IRAS) 186097 • Central Portfolio Management System (CPMS) 31771 (www.ukctg.nihr.ac.uk) • UCL Study Reference 15/0970 • REC reference 16/LO/1154 We have attached the following relevant documents: • Protocol • Covering letter and study summary Further information can be obtained from the sponsor by contacting info@i-hype.org Best wishes, <Names & contact details here>

Other things to do prior to data collection:
1. Ensure study leave is booked (if required) or plan to collect data on 'off' days.

a. Please note: a London wide pilot (and it's pilot) confirmed that you cannot simultaneously collect data and manage a list – both will suffer.

2. Inform the nurse in charge of recovery of the nature of the project. Please reassure nursing staff that during the pilot run (QUINCE, http://www.uk-plan.net/QUINCE), normal work and patient care were not affected.

3. Fill in and place posters ('*RAFT iHypE - Poster v4.2 14.7.16 IRAS 186097*') in pre-operative assessment and recovery areas.