





## How to sign up as an Associate PI

- 1. Google "Associate PI scheme NIHR" or follow this link
- 2. Click on Associate PI (API) registration form
- 3. Things you will need to provide:
  - a. Your details
  - b. The name and email address of the PI in your hospital
  - c. Your hospital address
- 4. Additional information needed:
  - a. Study name: CRAFFT: Children's Radius Acute Fracture Fixation Trial: A multi-centre prospective randomized non-inferiority trial of surgical reduction versus non-surgical casting for displaced distal radius fractures in children.
  - b. CPMS ID: 44878
  - c. Clinical Trials Unit: Oxford Clinical Trials Research Unit (OCTRU)
  - d. Study Manager: Kinzah Abbasi
  - e. Email: crafft@ndorms.ox.ac.uk
- 5. Enter the dates of your current placement
- 6. Once your application has been confirmed, you will receive an email from the Associate PI Scheme Central Team confirming your application.
- In this email, you will receive a link and an enrolment key for you to enrol on the Associate PI Scheme learning course on <u>NIHR Learn</u>. You need to complete the 6 month learning course and journal entries to evidence what you have done.
- 8. You need to supply a recent signed and dated CV and a valid certificate of GCP (within the last 3 years) to the study manager. Free online GCP NIHR training is available.
- 9. Download and complete your checklist during your 6 month rotation to record your activities. The PI will need to sign this form, as well as the study manager, at the end of your rotation.
- 10. A certificate will be issued by NIHR Central Team once the completed checklist has been submitted. This can be added to your training portfolio.





- 1. NIHR Online learning gateway register to create a free account. https://learn.nihr.ac.uk
- 2. You need to have a valid certificate of GCP within the last 3 years. Free online GCP NIHR training is available.
- 3. Optional granule course This course is designed to assist trainees with the practical skills to recruit patients into randomised surgical trials. It can be found here: <u>Granule Course Enrolment</u>

## Associate Principal Investigator Guide to setting up CRAFFT at your site:

- 1. Read the study documents (synopsis and protocol) which are available at <a href="https://crafft.octru.ox.ac.uk">https://crafft.octru.ox.ac.uk</a>
- 2. Recruit PI any consultant that is interested.
- 3. Establish department buy-in. If required, raise the trial at a departmental meeting.
- 4. Determine research support available at your site. If unsure, call "research nurses" via switchboard.
- 5. Find your local Clinical Research Network Manager at the NIHR website

Contact the research manager for "Division 6", which includes surgery.

They can sign-post you to everyone you need in your hospital.

- 6. Contact <a href="mailto:crafft@ndorms.ox.ac.uk">crafft@ndorms.ox.ac.uk</a> to request Site Feasibility Questionnaire (SFQ)
- 7. Complete SFQ. You will need the following information:
  - a. Research and Development contact (via switch board or via CRN manager)
  - b. Main contact usually a research nurse
  - c. Contact for clinical coding (as per point 7a)
  - d. Anticipated recruitment rates.
- 8. Schedule/ attend Site Initiation Visit with PI and CRAFFT trial team
- 9. Agree with local research team how and where patients will be screened/recruited (documented on REDCap) and where the electronic Investigator Site File (eISF) will be kept on your local intranet/ network computers.
- 10. Liaise with contracts department to facilitate localising and signing of site agreement
- 11.Liaise with R&D department to facilitate issuing confirmation of Capability & Capacity to conduct study (R&D approval)







Also check out the points needed to be a named PubMed collaborator (the above will help hugely – just recruit a few patients too!)