

## Distal Radius Acute Fracture Trial 3 – Cast versus Splint

National Institute for Health and Care Research Associate Principal Investigators
Scheme: Guide

## How to sign up for the NIHR Associate Principal Investigator (API) Scheme

- Visit the National Institute for Health and Care Research (NIHR) Associate
   Principal Investigators Scheme website for information about the scheme via
   this link
- 2. Here you will find information regarding the eligibility criteria to enter the scheme and how to register. Applications are open now
- 3. Things you need to register:
  - a. Approval from your local PI
  - b. Study details:
    - i. The DRAFT3-CASP Study
    - ii. CPMS ID 54355
    - iii. Clinical Trials Unit: Oxford Clinical Trials Research Unit
    - iv. Study Manager: Hannah Crook
    - v. Email: draft3-casp@ndorms.ox.ac.uk
  - c. Your details
  - d. The details (name and email) of the PI in your hospital
  - e. Your hospital address
- 4. Enter the dates of your current placement
- 5. Once your application has been confirmed, you will receive an email from the Associate PI Scheme Central Team confirming your application.
- 6. In this email, you will receive a link and an enrolment key for you to enrol on the Associate PI Scheme learning course on NIHR Learn (log-in required). You need to complete the 6-month learning course and journal entries to evidence what you have done.
- 7. 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.
- 8. A certificate will be issued by NIHR Central Team once the completed checklist has been submitted. This can be added to your training portfolio.
- 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.

- 10. Explore Learning at NIHR Learn NIHR Online learning gateway register to create a free account. <a href="https://learn.nihr.ac.uk">https://learn.nihr.ac.uk</a> for a range of resources and courses to develop your knowledge of clinical research.
- 11. 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: Granule Course Enrolment

## Associate Principal Investigator (aPI) Guide to setting up DRAFT3-CASP at your site:

- 1. Read study Protocol and visit the study website <a href="https://draft3.digitrial.com/">https://draft3.digitrial.com/</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 <u>NIHR website</u>. 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:draft3-casp@ndorms.ox.ac.uk">draft3-casp@ndorms.ox.ac.uk</a> to request and then complete a Site Feasibility Questionnaire (SFQ)
  - a. Once your SFQ is approved, study set up at your site will commence and the Local Information Pack (LIP) will be issued.
- 7. Schedule/ attend Site Initiation Visit with PI and DRAFT3-CASP trial team
- 8. Agree with local research team how and where patients will be screened/recruited and where the electronic Investigator Site File (eISF) will be kept on your local intranet/ network computers.
- 9. Liaise with contracts department to facilitate localising and signing of site agreement (as issued with the LIP)
- 10. 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!)