



Outcomes of Displaced Distal tibial fractures Surgery Or Casts in KidS (ODD SOCKS)

ASSOCIATE PI SCHEME

The Associate PI scheme is a hands-on experience in research for healthcare professionals including postgraduate doctors in training. It is endorsed by the National Institute for Health and Care Research (NIHR) to help you become involved in national, portfolio studies.

As an Associate PI, you may be involved in the study setup, recruitment and the care of trial participants within the study. You will work alongside the site's principal investigator (PI), who is the local clinical lead for this trial.

Your role will depend on what stage of setup your hospital is in. Associate PIs on previous children's orthopaedic studies have helped at all stages including:

- **Feasibility:** This process helps to identify if your hospital has any potential recruits for the trial and who will support the recruitment process locally. This includes: Identifying a local PI, helping complete the feasibility questionnaire and coordinating initial contact with the trials unit.
- **Pre-recruitment:** involves liaising with the local R&D team, helping to plan the flow of study participants in your hospital, attendance at site initiation visit.
- **Recruitment:** is the process of screening and identification of potential participants. The approach and recruitment of eligible patients and helping maintain study data and documents.

On completion of the Associate PI scheme, you will be provided with a certificate from the NIHR which can be added to your portfolio. You will also



have the chance to collect points to add to your sock-score to earn collaborative authorship on the final ODD SOCKS manuscript (see collaborator guide).

If you are interested in becoming an ODD SOCKS Associate PI for your hospital, then please read this guide. You will first need to register through the NIHR to join the scheme. Training is provided by the NIHR to support you as you then work with the local PI to setup and run the trial at your site. This is a great opportunity to master the research skills required for CCT and the scheme is an ideal chance to collect points towards recognition as a PubMed collaborator for the final publication.

If you have any questions about the scheme then feel free to get in touch

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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: Outcomes of Displaced Distal tibial fractures - Surgery Or Casts in KidS (ODD SOCKS). A multi-centre prospective randomized superiority trial of conservative versus surgical treatment for displaced distal tibial fractures in children
 - b. CPMS ID: **TBC**
 - c. Clinical Trials Unit: Oxford Clinical Trials Research Unit (OCTRU)
 - d. Study Manager: Kinzah Abbasi
 - e. Email: oddsocks@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.
7. 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](#). 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.

Other Links

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: [Granule Course Enrolment](#)



Associate Principal Investigator Guide to setting up ODD SOCKS at your site:

1. Read study Protocol and visit the study website www.oddsocks.org
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 oddsocks@ndorms.ox.ac.uk to request a 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. Anticipated recruitment rates.
8. Schedule/ attend Site Initiation Visit with PI and ODD SOCKS trial team
9. Agree with local research team how and where patients will be screened/recruited (documented on REDCap database) 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 (usually as part of the R&D team)
11. Liaise with R&D department to facilitate issuing confirmation of Capability & Capacity to conduct study (R&D approval)