



British Orthopaedic SCFE Surgery Study for Severe Stable Slips

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

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

1. 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 open from 05Jun2023
3. Things you need to register:
 - a. Approval from your local PI
 - b. Study details:
 - i. The Big BOSS Study
 - ii. CPMS ID 55962
 - iii. Clinical Trials Unit: Oxford Clinical Trials Research Unit
 - iv. Study Manager: Louise Spoons
 - v. Email: BigBOSS@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.
 9. 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](https://learn.nihr.ac.uk) NIHR Online learning gateway – register to create a free account. <https://learn.nihr.ac.uk> 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 BigBOSS at your site:

1. Read study Protocol and visit the study website <https://bigboss-study.digitrial.com/>
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 BigBOSS@ndorms.ox.ac.uk 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 BigBOSS 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!)