



DOLFIN Webinar - 6th July 2023

NIHR Associate Principal Investigator (PI) Scheme



Associate Principal Investigator (PI) Scheme



- **What:** NIHR Associate PI (API) Scheme is a 6 month in-work training/mentorship opportunity, providing practical experience of working on an NIHR portfolio trial.
- **Who:** Healthcare professionals starting their research career, who would not normally take part in clinical research in day-to-day role.
- **Outcome:** Associate PI's receive formal recognition through the certification of Associate PI status, endorsed by the NIHR and Royal Colleges.



Which studies are eligible for the scheme?

Study eligibility criteria includes:

- Non-commercial and on NIHR portfolio.
- Multi-centered.
- At least 6 months of recruitment activity left.
- Clinical Trials Unit (CTU) or equivalent involvement.
- Specialty included in Supported Specialities and Royal College Endorsements list).





is registered with the
NIHR API Scheme.



Who is eligible to be an API?

- Any qualified NHS health and care professional (doctor, nurse, midwife, AHP, dietician, pharmacist, etc.). Includes Trainees from FY1 upwards.
- Not eligible if your role is specifically funded to work on research e.g. research nurse.
- Must be willing to make a significant contribution to the conduct and delivery of the study at a local level.
- Applicants can only be an Associate PI for one study at a time.
- One Associate PI, per study, per site at a time (1 Associate PI to 1 PI).
- Commitment of at least 6 months (should be during study recruitment period).
- Must register prospectively - retrospective recognition is not possible.
- Associate PIs must gain prior approval from their Local PI
- Must be GCP trained.
- Research CV required
- Must be on study delegation log.



The Process for an Associate PI



- ✓ Speak to Local PI of chosen study to get their endorsement to join the scheme
- ✓ Register or login to NIHR learn. Complete online registration form on the NIHR Associate PI Scheme website.
[Associate PI Scheme Applicant Registration Form](#)
- ✓ Associate PI Trainee works alongside Local PI for 6 months of the study at the site, Local PI acts as a mentor during their time on the Scheme.
- ✓ Complete Checklist of mandated study activities and complete Associate PI Scheme Learning Pathway in NIHR Learn.
- ✓ Checklist signed off by Local PI and National Study Coordinator.
- ✓ Associate PI Scheme team issues a Certificate, confirming Associate PI status
- ✓ Scheme encourage trials to acknowledge APIs in publication from the study in a PubMed searchable way, normally in the appendix as a collaborator.



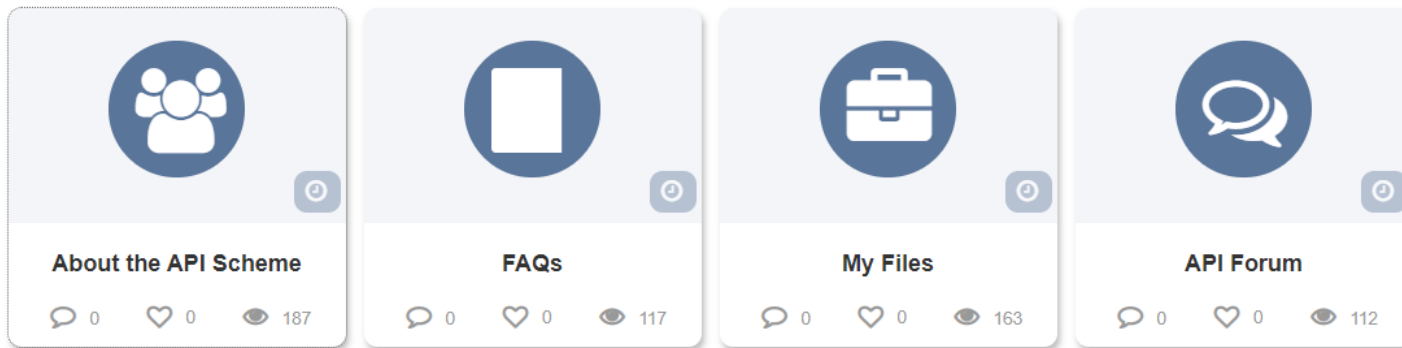
What would an API do?

- Local PI remains responsible for study at site.
- Local PIs will act as mentors to their Associate PI, helping them to understand what it means to be a Local PI.
- Associate PIs must demonstrate involvement in each of the core activities:
 - ✓ Team activities
 - ✓ Study management/compliance activities
 - ✓ Patient related activities



Associate PI Scheme - Checklist Activities

- Signature on study-specific delegation log
- Dissemination to the department
- Engagement with staff, research team meetings (Diary of research team meetings)
- Site log, protocol amends, data returns and quality
- Screening logs, recruitment/consent of patients or facilitating consent of patients
- Train staff (GCP, protocol)
- Deputising for PI
- PPI activities



NIHR | National Institute for Health Research

*Please Note- Applicants need to download and save a copy of this checklist and edit your version, we cannot give you edit access to the live document.

Associate Principal Investigator (PI) Status Checklist

Associate PI Name: _____

Study Name: _____

Specialty: _____

CPMS: _____

Site/GP Practice: _____ ODS Code(if applicable): _____

Clinical Trials Unit: Associate PIs should fulfill the criteria below. This form should be completed during the Associate PI time period. Towards the end of the rotation or time period, the Associate PI applicant should meet with the local PI (and research delivery team).



Associate PI Scheme – GMC Acknowledgment

“

*The **Associate PI Scheme** provides participating health and care professionals with **hands-on** research experience as a development opportunity that addresses many of the **GMC’s generic professional capabilities** through a **research lens**. It also supports doctors to demonstrate many of the expectations in **Good Medical practice for appraisal purposes**, and assists in further embedding a culture of research.*

”

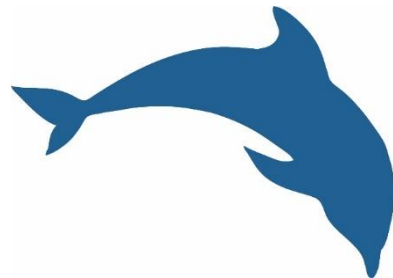
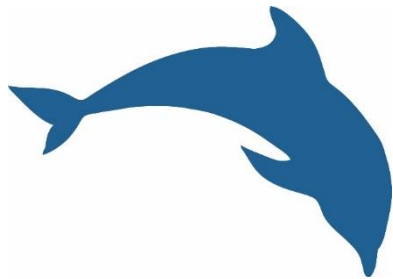
- General Medical Council



DOLFIN Associate PI's

- From 25 recruiting sites, 11 sites currently have an API.
- 2 sites have had 1 API completed scheme, second API.
- API's included in study communication e.g. newsletters/ emails, invited to events e.g. collaborator's day, webinars.

We want to encourage more sites to use the scheme.



DOLFIN API tasks

- Approach parents and take consent – particularly helpful for HIE infants and out of hours.
- Work with team to identify barriers and resolutions.
- Support staff training – administering supplement.
- If medically trained can support safety reporting (causality assessments), clinical queries, prescribing (if applicable).
- Assisting with data collection e.g. HIE questionnaire.
- Promote trial across hospital and amongst colleagues – putting up staff posters, grand rounds, MDT's, staff emails.
- Cannot sign off other people on delegation log, only PI can do this.



Benefits of the Associate PI Scheme

For the API

- Experience of research with mentoring from PI
- Learn about the challenges and practicalities of delivering a portfolio study
- Formal recognition through certification of Associate PI status, endorsed by the NIHR and Royal Colleges (can be added to CPD training portfolio).
- Career development and new skills for CV
- Networking / collaborating with multi-disciplinary team
- Support colleagues and promote research at site
- Associate PIs should be acknowledged in the primary publication(s) from the study

For the PI

- Additional support with the delivery of the study
- Can cover PI duties in case of absence
- Developing the PIs of the future

For Study Team/CTU

- Increased support for the trial at sites - managing delegation logs, safety reporting etc.
- Speedier delivery
- Enhanced Recruitment
- Increased buy-in from clinical team

For the Patient

- Increased opportunities to be involved in high-quality research



Feedback from Associate PIs

"Participating in the Associate PI Scheme has opened doors for me to gain a greater understanding of research within the NHS. I gained new skills that I can use in my current role, and the development opportunities have also helped contribute towards my revalidation. The application process is easy and I gained lots of transferable skills."

- Amanda Hill, Hepatology Nurse Specialist and Associate PI Alumni

"Excellent scheme for getting HCPs more involved in research!"

"This is the first time I am able to understand the process of NHS research"

"Fantastic opportunity to take part in research and gain detailed experience. I'm learning about what conducting a clinical trial truly entails"

"It has been great playing such a leading role while being fully supported by the research team. I have also enjoyed putting the GCP principles into everyday practice"

"I am learning skills that will help me as I progress in my career"



How to get involved

Go to the NIHR Associate PI Scheme Website:

www.NIHR.ac.uk/AssociatePIScheme

To register to be an Associate PI,
submit an [Application Form on NIHR
Learn](#)



Associate PI
Trainee Applications

Before you get started, we highly
recommend watching the “How
to” videos [available here](#)



How to apply Videos,
Resources & FAQs



Further Resources

Website: [Associate Principal Investigator Scheme](#)

Contact: associatepischeme@nihr.ac.uk

Videos

- Introduction to scheme: <https://youtu.be/at5PM61X0Yw>
- How to apply: <https://youtu.be/klt28ZUg280>

FAQ's

- [Associate PI Scheme FAQs.](#)



Next steps for API's

To further support an individual's pathway into research, resources available include:

- PI Learning Directory tile – for those interested in gaining more research knowledge and taking on the role of PI in the future.
- Making Local Connections tile - to provide you with the details of Local Workforce Delivery Leads.
- Alumni Forum - where Associate PIs can connect with each other and share their experiences of the Scheme, what they have done since the Scheme and share any ideas of what can be done after the Associate PI Scheme.
[Associate PI Scheme Alumni Area](#)

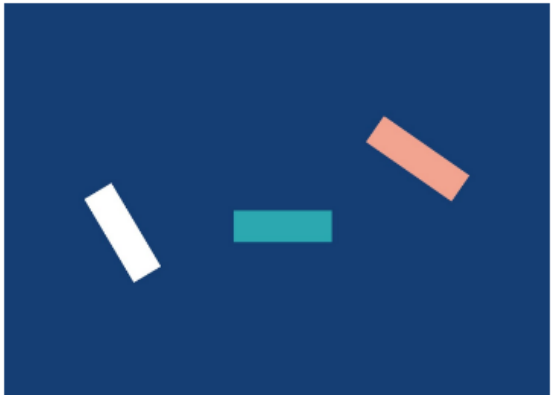
New Associate PI Scheme Study Teams Forum

- NIHR have partnered with CHAIN (the Contacts, Help, Advice & Information Network), to introduce 3 special interest sub-groups onto their network.
- 'Associate PI Scheme Study Teams' group - a platform for sharing good practice with other Study Teams e.g. keeping API Trainees engaged, identifying more healthcare professionals to take part.
- **CHAIN Membership** is free, visit the CHAIN joining site at <https://www.chain-network.org.uk/join.html> to register.



Toolkit

We have created toolkits full of useful information and recommendations for our Associate PI's, Local PI's and the National Study Team. We recommend that if you are thinking about undertaking, or have taken on one of these roles, then you read your relevant toolkit thoroughly.



[Associate PI Toolkit](#)



[Local PI Toolkit](#)



[National Study Team Toolkit](#)



Webinars

- **The Research Learning Lectures** - series of lectures covering topics relating to basic science, clinical trial methodology and statistics. [Webinar Recordings page.](#)



For further information,
visit the website at

www.NIHR.ac.uk/AssociatePIScheme

or scan the QR code below

