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NIHR CRN Associate Principal Investigator Scheme

Associate PI Scheme – Background

Developed by

- West Midlands Research Collaborative
- Birmingham Surgical Trials Consortium
- Birmingham Clinical Trials Unit
- West Midlands NIHR Clinical Research Network

Currently open to NIHR Portfolio studies led by

- Surgery
- Cancer
- Ear, Nose and Throat
- Gastroenterology
- Hepatology
- Ophthalmology
- Reproductive Health & Childbirth
- Haematology
- Anaesthesia, Peri-Operative Medicine & Pain Management
- Trauma & Emergency Care

The Scheme is being actively rolled out to other specialties and we aim to launch into all specialties by the Autumn

Endorsed by the NIHR Clinical Research Network and the following Royal Colleges; Royal College of Anaesthetists, Royal College of Emergency Medicine, Royal College of Physicians, Royal College of Radiologists, Royal College of Surgeons (England), Faculty of Intensive Care Medicine, Royal College of Ophthalmologists, Royal College of Obstetrics and Gynaecoogists, Royal College of Midwives

Associate PI Scheme – Aims

- To integrate clinical research into clinical training.
- To develop doctors, nurses and allied health professionals to be PIs of the future.
- To engage, recognise and promote doctor, nurse and allied health professional engagement in NIHR portfolio research in a consistent manner.
- To increase opportunities for patients to be involved in high quality research to improve care.

Associate PI Scheme – Structure

- Open to any doctor, nurses and AHPs willing to make a significant contribution to the conduct and delivery at a local level. The scheme is not open to those who are funded to work on research, such as Research Nurses.

- Participation in the Associate PI Scheme does not absolve local PIs of their responsibilities at site. Local PIs will act as mentors to their Associate PI.

- Commitment of at least 6 months will be required for gaining Associate PI status.

- Must register prospectively- retrospective recognition is not possible

Benefits of the Associate PI Scheme

For the Associate PI

- Experience of research - able to contribute to the conduct and delivery of a study at local level with the oversight of the local enthusiastic PI.
- Learns about the challenges and practicalities of delivering a portfolio study, understands the responsibilities associated with the PI role, and their participation is recognised through certification for their CPD portfolio.
- Associate PIs will be acknowledged in the primary publication(s) from the study, which will be defined upfront on an individual trial basis.

For the PIs

- Additional support with the delivery of the study
- Play a part in developing the PIs of the future

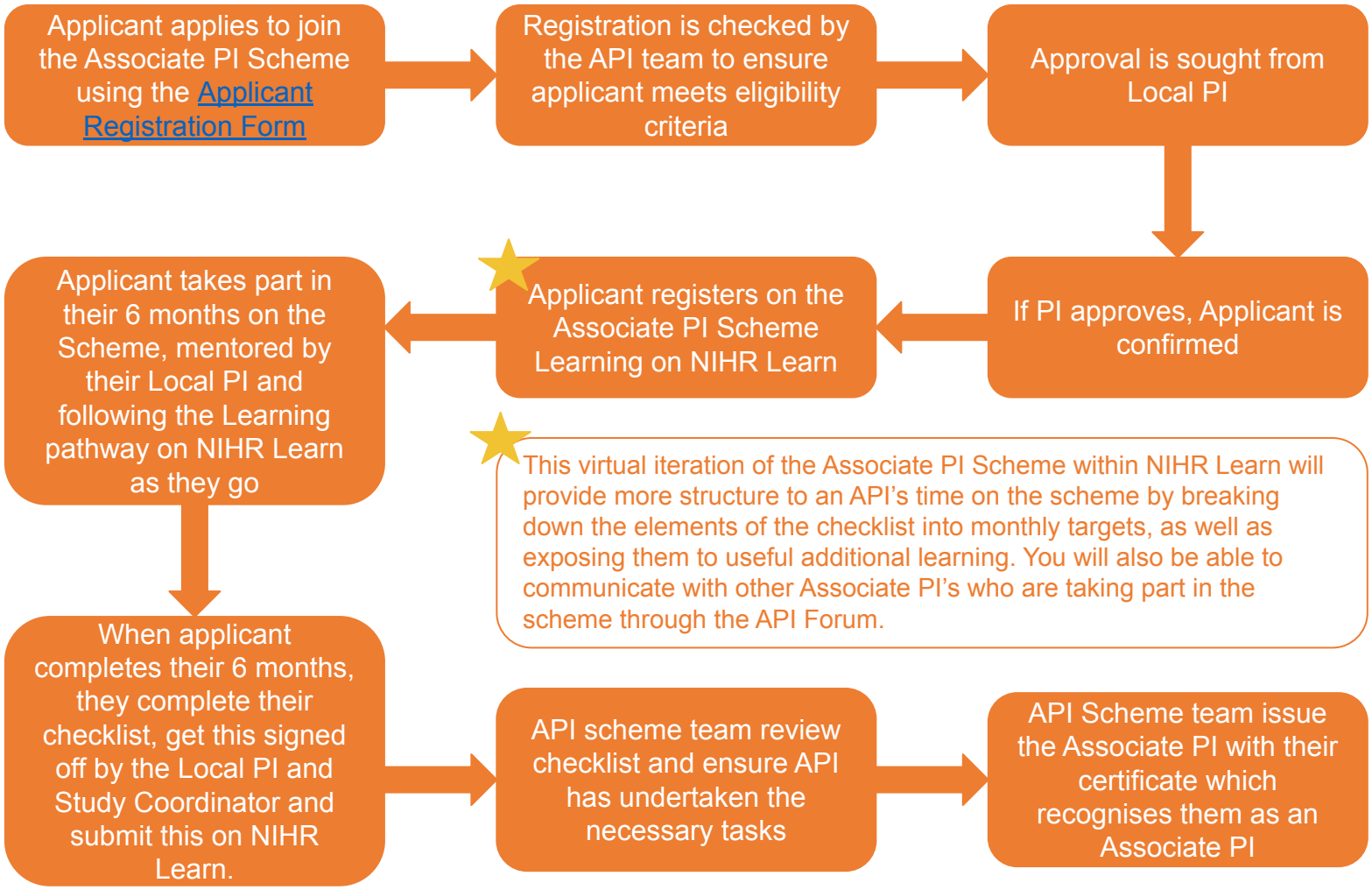
For CTUs

- Increased support for the trial at sites- managing delegation logs etc
- Speedier delivery

For the Patients

- Increased opportunities to be involved in high- quality research

Associate PI Scheme - Applicant Registration Process



Associate PI Scheme - Applicant Eligibility Criteria

- The Scheme is currently open to applicants from the following specialties: Cancer, Ear, Nose & Throat, Gastroenterology, Hepatology, Ophthalmology, Surgery, Reproductive Health & Childbirth, Haematology, Anaesthesia & Peri-Operative Medicine & Pain Management and Trauma & Emergency Care.
- Associate PIs can only apply to be Associate PIs for studies that are registered on the Associate PI Scheme.
- Applicants can only be an Associate PI for one study at a time.
- We only allow one Associate PI, per study, per site. In some cases we allow multiple Associate PIs but they must be from different specialties (for example, one API for Cancer and one API for Surgery) if both specialties are relevant to the study.
- The scheme is open to any Doctor, Nurse or Allied Health Professional who wants to gain knowledge of what it means to deliver an NIHR portfolio trial.
- We do not allow those who are funded to work on research already to join the scheme (such as research nurses) as this scheme is for those people who would not normally be involved in research.
- Associate PIs must be able to commit to 6 months of working on a study at their site to take part in the Scheme.
- Associate PIs must gain approval from their Local PI that they are happy to support them before they apply for the scheme.

Associate PI Scheme - The role of the Local PI

- The Local PI will still be legally responsible for the study at their site. Their responsibilities to their Associate PI will be to generally mentor, support and guide them to help deliver the study at the local level.

- The role of the Local PI to provide mentorship and to pass on their knowledge and expertise to their Associate PI to help understand what it means to deliver a clinical trial whilst at the same time, ensuring you have continued oversight of all aspects of the trial at site.

- It is expected that the Local PI will meet regularly with the Associate PI, supporting the Associate PI to present the study at departmental meetings, assist and lead the Associate PI when dealing with challenging aspects of trial delivery or questions about how the trial will run and to guide the Associate PI through interactions with R&D and other departments as appropriate.

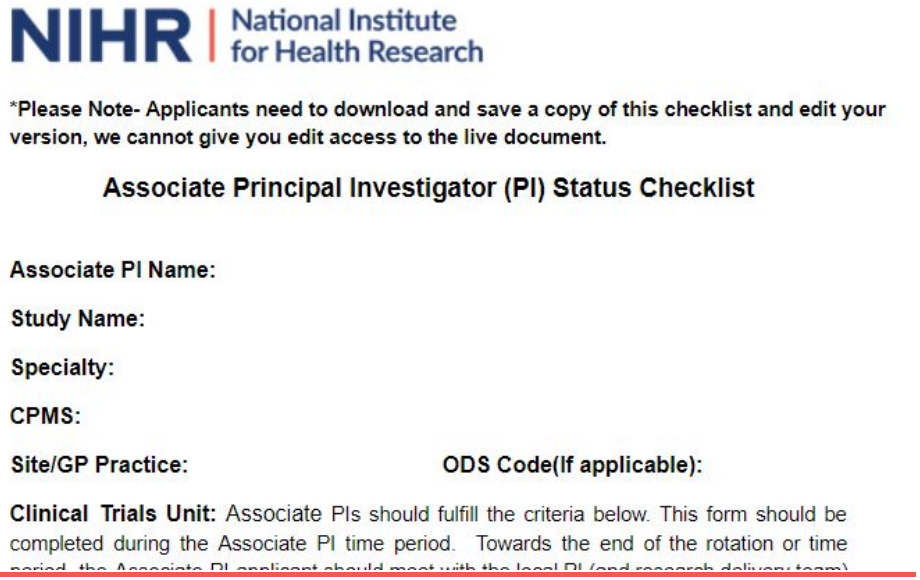
- We would recommend that Local PIs meet with their Associate PI at least once every 2 weeks to keep up to date on their Associate PI's progress and to ensure they feel supported and are having a chance to undertake all the tasks on their checklist. The PIs and APIs who obtain the most benefit from the scheme tend to work very closely together and meet on a weekly basis.

- Towards the end of their period of time as an Associate PI (usually around 6 months) the applicant will formally meet with the local PI in order to review the checklist and ensure all targets have been met. By signing the checklist, the PI is taking responsibility for confirming that the Associate PI applicant has fulfilled the requirements to be recognised as an Associate PI.

Associate PI Scheme - The Checklist

We ask Associate PIs to fill out a checklist of activities during their time, these activities include;

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



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*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

Associate PI Scheme - How to Register

Go to the NIHR Associate PI Scheme Website :
https://www.nihr.ac.uk/documents/associate-principal-investigator-pi-scheme/25040

To register yourself as an Associate PI, complete the Associate PI Scheme Applicant Registration Form


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Associate PI Scheme - Applicant Registration Form

This form should be completed by applicants wishing to register for the Associate PI scheme.

If you would like to apply for Covid-19 Urgent Public Health studies, please use the form at the following link:
https://docs.google.com/forms/d/e/1FAIpQLSc-y-Y_qql42hFkznZk_eZLCNkCq7liUYZkiI4I0Kxy0nDykQ/viewform

The scheme has been endorsed by the NIHR Clinical Research Network and the following Royal Colleges: