

01_What is my role as the Local PI in the Associate PI Scheme?

Legal Responsibilities

Your legal responsibilities do not change as a Local PI when you begin working with an Associate PI on the Associate PI Scheme.

As the Local PI, you are still legally responsible for the study at your site.

Time Commitment

An Associate PI is expected to take part in the Associate PI Scheme on top of performing their core day-to-day role. We understand this is a big commitment so we do not mandate how many hours per week someone commits to the Associate PI Scheme, as we understand that this will vary.

We recommend that an Associate PI performs the Associate PI role for approximately 2-3 hours per week, as a rough guideline. So you would be mentoring your Associate PI approximately 2-3 hours per week.

We mandate that an Associate PI must work within the Associate PI role for 6 months in order to gain all of the relevant experience to be officially recognised as an Associate PI. Associate PI's will generally be involved in a study at a single site for 6 months. This may be partly during the set-up phase and during follow-up of patients, but must include recruiting participants.

Mentorship

As the Local Principal Investigator, your main role in regards to the Associate PI Scheme is to mentor, support and guide your Associate PI during their 6 month tenure on the Scheme.

For a lot of Associate PIs, this will be their first experience of delivering research so you need to mentor them on what is involved in delivering a study at a site. You need to pass on your knowledge and experience of leading on a study at a site so they understand the practicalities and challenges involved.

You need to support them to complete their <u>Associate PI Scheme Checklist</u>. This is a checklist of activities to help Associate PIs gain understanding and skills relating to study delivery and management.

We recommend that you look at this checklist with your Associate PI and discuss how they can complete all the activities, potentially setting some goals, targets, or deadlines as you see fit.

Meeting with your Associate PI

We recommend that you meet regularly with your Associate PI to check in on their progress, and to understand where you can offer more support and guidance.

The Associate PIs that have had the best experience advised that they met weekly or bi-weekly with their Local PI.

We have put together this <u>Template Agenda</u> that we have given to Associate PIs that we will encourage them to use in meetings with you as their Local PI.



Encouraging your Associate PI to interact with the Clinical Trials Unit

We encourage Associate PIs to interact with the National Study Team Representative/Trial Manager at their site so they can understand what the role of the CTU is in running a study, and so that the National Study Team Representative/Trial Manager can support the Associate PI in completing some of the activities on the Associate PI Scheme checklist.

Please encourage your Associate PI to make contact with the National Study Team Representative for your study so that they can build a relationship with them.

Approving Associate PIs for the Scheme

As a Local PI, we will seek your approval for an applicant to join the Associate PI Scheme, as it is important that you are happy to mentor them during their time on the Scheme and feel that they will be able to undertake all of the activities on the Associate PI Scheme Checklist.

For more information about this, please refer to Document <u>02 What are my responsibilities in</u> regards to approving a prospective Associate PI for the Associate PI Scheme?

Signing of an Associate PIs Checklist

Towards the end of an Associate PI's 6 month tenure, the applicant will meet with the Local PI in order to review the Checklist and if completed satisfactorily, the Local PI will sign the checklist.

It is therefore imperative that the Local PI upholds the rigour and status of the Scheme by making sure that the Associate PI has completed all of the relevant activities to receive certification, as well as ensuring this is well evidenced on their checklist.

For more information on this, please refer to document <u>03_What are my responsibilities in regards to signing off an Associate PI's Checklist?</u>

Suggesting Studies join the Associate PI Scheme

If there is a study running at your site that is not already registered, and you think it would benefit from being part of the Associate PI Scheme then we would encourage you to speak to the CI of that study about registering the study for the Scheme. Please refer to document <u>05_If</u> there is a study running at my site that I think should be part of the Associate PI Scheme, how do I make this happen?