 

**Associate Principal Investigator (PI) Status Checklist**

Associate PI Name:

Study Name:

CPMS Number:

Site:

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 nurse) in order to review the Checklist and if completed satisfactorily, the PI should sign it off. The Checklist should then be forwarded to the Study Coordinator/Trial Manager for final confirmation that the activities described have been undertaken.

**Associate PIs MUST register prospectively via the NIHR website (**[**https://www.nihr.ac.uk/explore-nihr/specialties/surgery.htm**](https://www.nihr.ac.uk/explore-nihr/specialties/surgery.htm)**). If applicants are not registered prospectively and submit a checklist of activities their application will be rejected.**

**Participation in the Associate PI Scheme does not absolve local PIs of their responsibilities at site. The Local PI remains responsible for the oversight of the trial at site, including the activities of the Associate PI.**

**All activities undertaken by the Associate PI must be undertaken in line with GCP and, for CTIMP trials, the Medicines for Human Use Clinical Trials Regulations.**

***Core activities (Associate PIs must demonstrate involvement in each of the core activities)***

Team activities

* Be a member of the site research team as evidenced by their signature on the study-specific site delegation log.
* Be involved in the study at a single site for at least 6 months. This may be partly during the set-up phase but must include recruitment or follow up of patients.



* Disseminate the study to the local department/hospital. This must include presentation at a departmental meeting along with other activities to engage with local consultants, junior doctors, nurses and allied health professionals as appropriate. This may also involve engaging with other departments depending on the study e.g. anaesthetics and can take place both at the start of a study and quarterly thereafter.



* Regular engagement with the PI and the rest of the research team, such as the research nurse and junior doctors/nurses/allied health professionals to facilitate successful study delivery. Aspects to cover may include review of the patient pathway, site log maintenance, recruitment progress, protocol amendments, data returns and quality.



* Work with the PI to ensure that the delegation log is correctly completed for each member of the research team, particularly rotating junior doctors, and this includes the Associate PI applicant.



* Help the PI to ensure that every member of the research team has up to date GCP training and has supplied this certificate and a signed CV to the research nurse.



* Assist the PI to ensure that all staff delegated to work on the study are adequately informed of protocol requirements and trained in study procedures. This will primarily involve educating fellow junior doctors/nurses/allied health professionals who are working on the study.



* Diary of research team meetings - this should include meetings with the PI, research nurses and the rest of the research team. This is expected to be at least monthly.



Study management/compliance activities

* Perform regular checks by reviewing screening logs to ensure that appropriate patients are screened for inclusion and recruited to the study. This may be conducted alongside the local research staff, if present.



Patient related activities

* Be personally involved in the recruitment, consenting and/or follow-up of a defined number of patients. The recruitment target will be pre-determined by the trial CI and local PI.

All activities undertaken must be in line with the Clinical Trial Regulations (as appropriate) and local R&D requirements. The local PI should ensure that the Associate PI is permitted, by R&D, to take consent for the study.



***Additional activities (these activities may or may not be appropriate for the study and are not mandatory for Associate PI status)***

* Be involved in a variety of additional study-related activities such as interacting with the Clinical Trials Unit, Clinical Research Network, deputising for the PI at investigator meetings, collaborating with Associate PIs at other centres.



* Please document any Patient and Public Involvement (PPI) activities.



* Please document any involvement in Trial Management Group meetings.



* Please document any training courses which you have been on (eg. GCP, GRANULE, INSPIRE, FUNDAMENTALS) .



***Declarations:***

We confirm that the Associate PI applicant has taken part in the activities described above. The applicant has provided key assistance with the local delivery of the study specified at the start of this document.

PrincipaI Investigator (PI)

* PI name:
* PI email address:
* PI signature:
* Date of signature:

Clinical Trials Unit representative (Study Coordinator/Trial Manager)

* Clinical Trials Unit representative name:
* Clinical Trials Unit representative email address:
* Clinical Trials Unit representative signature:
* Date of signature:

Associate PI applicant:

* Associate PI applicant name:
* Associate PI email address:
* Associate PI applicant signature:
* Date of signature:

A copy of the completed form should be forwarded by the Associate PI applicant to the Clinical Trials Unit representative responsible the study for which this accreditation is applicable.

The fully signed Checklist should be scanned and emailed to: associatepischeme\_surgery@nihr.ac.uk.

The NIHR CRN will then issue a certificate confirming Associate PI status.