

Academy of Clinical Research Professionals
Policy on Eligibility for the Certified Principal Investigator (CPI) Program
Effective as of the March 2017 Examination

POLICY

All applicants for the Certified Principal Investigator (CPI) program must meet all of the eligibility requirements stated in the *CPI Candidate Handbook* and on the application form itself in order to be approved to take the CPI examination.

Applicants are required to submit documents, as outlined below, to demonstrate that he/she has served as a Principal Investigator for clinical trials for at least two (2) years of the past five (5) years with enough detail so as to sufficiently document and demonstrate achievement of the required minimum experience performing the Essential Duties of a Certified Principal Investigator.

The CPI Essential Duties are defined as:

- Responsible for the safe and ethical conduct of a clinical trial;
- Evaluates the study proposal and decides on participation;
- Facilitates or verifies formal approvals according to regulatory requirements and International Conference on Harmonisation (ICH) Good Clinical Practice (GCP);
- Ensures that all site initiation activities are performed to start and conduct the study;
- Participates in the selection of trial subjects according to the recruitment strategy;
- Performs or supervises the conduct of study-related procedures and monitors the safety of the trial subjects and investigational staff;
- Collects accurate and verifiable data and other essential study documents;
- Ensures compliance with regulatory requirements and ICH GCP, the protocol and the handling of the investigational product;
- Communicates with subjects, sponsor’s personnel, and Institutional Review Board
- Ensures adequate close-out of the study

Applicants must document his or her role as a Principal Investigator (PI) during at least two (2) out of the most recent five (5) years by submitting copies of at least one (1) of the following documents for each of those two (2) years.

Requirements	Documentation to be Submitted
Education	<ul style="list-style-type: none"> ▪ Doctorate level degree (DDS, MD or equivalent degree such as DO, MBBS or MBChB, PhD, PharmD, DNP) OR ▪ A licensed Physician’s Assistant or Nurse Practitioner who has served in a PI role, as documented below; current license required and must be submitted with application ▪ CV must reflect name of educational institution, location (city, country), title of degree and date awarded
Experience	For at least <u>TWO (2)</u> of the most recent five (5) years: <ul style="list-style-type: none"> ▪ 1572 / PHS 398 / QIU (or equivalent) OR ▪ IRB/IEC approval letter to conduct the study OR ▪ Protocol approval letter for the study OR ▪ Signed copy of an investigator agreement/protocol signature page OR ▪ Other regulatory authority document verifying your role as a Principal



	Investigator on the clinical trial being submitted in support of eligibility <i>Any proprietary details may be blocked out.</i>
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Clinical Research Certifications

The Academy acknowledges that there is a shared knowledge base between CCRA and CCRC certificant holders and those who may seek the CPI designation. Any candidate for the CPI designation who has a current CCRA or CCRC designation will have achieved a valid substitute for one (1) year of the required professional experience performing the essential duties of a CPI.

Academic Qualifications in Clinical Research

The Academy considers applicants who have completed a formal clinical research education program that meets the following standards to have achieved a valid substitute for one (1) of the required two (2) years of professional experience performing the Essential Duties.

Acceptable programs must:

- Be at least 216 hours in length **and**
- Cover content that substantially maps to the topics found on the current [CPI Detailed Content Outline \(DCO\)](#) **and**
- Be accredited by an accrediting agency recognized by the Council on Higher Education Accreditation (CHEA) or be authorized by the appropriate regulatory authority in the country in which the program operates.

If an applicant submits an application using an educational program as a one (1) of the required two (2) years of professional experience performing the Essential Duties, then the following information must be included on the applicant's CV and a certificate of completion/transcript must also be submitted:

- Name of school
- City and country in which the school is located
- Program title
- Name of organization that accredits the institution providing the program
- Dates attended (From-To)

The Academy reserves the right to verify any and all employment information submitted on an applicant's CV or job description at any time during the process of certification or thereafter. If an applicant is found to have falsified or misrepresented his/her documentation, it is grounds for revocation of eligibility and/or certification status.

