Academy of Clinical Research Professionals

Policy on Eligibility for the Certified Clinical Research Associate (CCRA) Program

Effective as of the March 2017 Examination

POLICY

All applicants for the Certified Clinical Research Associate (CCRA) program must meet all of the eligibility requirements stated in the *Certification Candidate Handbook* and on the application form itself in order to be approved to take the CCRA examination.

Applicants are required to submit both

- 1) a copy of a current curriculum vitae (CV) or resume and
- 2) a copy of job descriptions for each of those positions used to demonstrate eligibility

with enough detail so as to sufficiently document and demonstrate achievement of the required minimum number of hours of employment performing the Essential Duties of a Certified Clinical Research Associate.

The CCRA Essential Duties are defined as:

- Verify that the research site investigator(s) and study personnel are conducting the study according to the clinical protocol, "Good Clinical Practices", and regulatory requirements to ensure protection and ethical treatment of human subjects;
- Ensure identification and reporting of safety issues, when applicable, from research site staff to the sponsor and the IRB/IEC;
- Perform monitoring activities per the monitoring plan (e.g. verification of source documents and eCRF/CRFs, site communications, follow up on data anomalies, etc.)
- Review accuracy and completeness of site records (i.e., essential documents, query resolution, and other data collection tools);
- Ensure accountability of Investigational Product and related supplies are performed, when appropriate;
- Ensure complete reporting and proper documentation of monitoring activities;
- Conduct routine monitoring visits (on site or remotely) independently from the investigative site study staff;
- Ensure the site is identifying issues and implementing corrective and preventive actions to ensure inspection readiness.

Applicants must document a cumulative, minimum of number of hours of employment performing the Essential Duties, based on his/her highest level of education completed. If the applicant's experience is within 120 hours of the requirement, by the first day of the exam window, full consideration will be given toward eligibility.



Highest Level of Education Completed	Minimum Hours Performing Essential Duties
■ Bachelor's degree (or higher)	3,000 hours
■ LPN, LVN, RN, or Associate's degree	4,500 hours
 Other, such as Medical Assistant, Lab Technician <u>OR</u> High School diploma 	6,000 hours

Clinical Research Certifications

The Academy acknowledges that there is a shared knowledge base between CCRC and CPI certificant holders and those who may seek the CCRA designation. Any candidate for the CCRA designation who has a current CCRC or CPI designation will have achieved a valid substitute for 1,500 hours of the required professional experience performing the essential duties of a CRA.

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 1,500 hours of the required 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 <u>CCRA Detailed Content Outline</u>
 (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 substitute for 1,500 hours of work 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.



