



Academy of Clinical Research Professionals

Policy on Continuing Competency and Maintenance for the CCRC, CCRA and CCTI Program

POLICY

The goal of the Certification process is to ensure, as much as possible, the continuing competence of each certificant and maintain the professional standard of those engaged in clinical research. There are a number of professional activities that can contribute to that goal.

The purposes of the Continuing Competency requirements established by the Academy are that CCRCs, CCRA, and CCTIs continue to:

- obtain current professional development information;
- explore new knowledge in specific content areas;
- master new clinical research-related skills and techniques;
- enhance approaches to effective clinical research, both within their specified job role and beyond;
- further develop professional judgment;
- conduct clinical research in a safe and ethical manner.

The Academy expects that clinical research professionals engage in lifelong development to maintain and improve knowledge and skills for competent practice. This includes continuous self-assessment to identify professional strengths and learning needs, establishment of short- and long-term goals for individual professional development, and selection of appropriate professional development to meet these goals.

Candidates for Maintenance should choose those professional development activities that provide them with the most benefit, keeping in mind that the length and rigor of a program contribute to its value. Advance planning for Professional Development enables candidates to choose more appropriate courses and also to control expenses more effectively. Professional development programs provide one of the main methods for keeping up with professional practice.

Maintenance of Certification is required every two (2) years. Each candidate for Maintenance must demonstrate that he/she meets the current requirements in order to successfully recertify and be permitted to continue to use the designation.

To successfully maintain Certification, each candidate must submit 24 points as part of the Maintenance application. **At least twelve** (12) of those 24 points must come from participation in research-related professional development programs.

REPORTING PERIOD FOR POINTS

Applicable activities to satisfy the Maintenance requirements must fall within the appropriate timeframe for a candidate's maintenance period.

Certification Expiration Date	24 Month Reporting Period
May 31	June 1 (year 1) – May 15 (year 2)



November 30

December 1 (year 1) – November 15 (year 2)

PROFESSIONAL DEVELOPMENT PROGRAM TOPIC AREAS

Candidates for Maintenance can take professional development offerings in two (2) areas:

- Research Topics
- Disease/Bodily System/other Healthcare Topics

RESEARCH PROGRAM TOPICS

For Maintenance purposes, Research Topics are defined those that cover the actual “practice” of clinical research and follow topics covered on the Detailed Content Outline (DCO) for your designation. These topics should cover transferrable knowledge and skills, not those specific to your workplace, such as company SOPs or specific software. Examples of Research Topics include, but are not limited to:

- Trial Management
- Investigational Product Management
- Protocol Development
- Safety
- Human Subject Protection
- Document Management
- Trial Oversight
- Ethics
- Adverse Events
- Informed Consent
- Good Clinical Practice (GCP)
- ICH Guidelines
- Regulatory Issues
- Monitoring
- Statistics

DISEASE/BODILY SYSTEM/HEALTHCARE PROGRAM TOPICS

Disease/Bodily System/Healthcare Topics are those that deal with the prevention, treatment, and management of illness and the preservation of physical well-being. Training to gain access or query a specific database or software, even if healthcare related, is not acceptable.

Courses pertaining to a particular disease are generally considered to be Disease/Bodily System/Healthcare Topic hours. Examples include, but are not limited to:

- Pharmacology
- Medical devices
- Palliative / Hospice care
- Psychiatry
- Oncology
- Endocrinology



- Cystic Fibrosis
- Results of clinical trial studies
- Advanced Cardiac Life Support (ACLS) (This course is only acceptable once during the lifetime of the certificant's Certification tenure.)

For general participation in workshops, seminars, conferences and in-service trainings, points are awarded according to the actual amount of time spent under instruction at a ratio of 1:1. Forty-five (45) – sixty (60) minutes of instruction = one (1) education point; one (1) semester credit = fifteen (15) points.

Points are not awarded for sessions that are fewer than forty-five (45) minutes in length but can be pro-rated for sessions exceeding sixty (60) minutes (i.e., a session one hour and fifteen minutes in length = 1.25 points)

All web-based training to be applied to the requirements **must** result in a certificate that indicates the number of hours awarded for successful completion. The Academy cannot determine the number of points for web-based training for a candidate. The Academy reserves the right to request certificates of attendance and/or transcripts from any and all courses.

Activity	Time Spent	Contact Hours	Points on Maintenance Application
Professional Development Session <i>(non-accredited programs)</i>	< 45 minutes	No points awarded	0 points
	45-60 minutes	1 contact hour	1 contact hour = 1 point
	90 minutes	1.5 contact hours	1.5 contact hour = 1.5 points
Activity Awarding CMEs	60 minutes	1 CME	1 CME = 1 point
Course Awarding CEUs	60 minutes	1 CEU	1 CEU = 1 point
University Course	1 semester	1 semester credit	1 semester credit = 15 points

ACCREDITED PROFESSIONAL DEVELOPMENT PROGRAMS

It is anticipated that the majority of programs that a candidate for Maintenance of Certification will submit in support of his/her application will come from programs that have some sort of accreditation. If the program does not have accreditation from a known accrediting body, the applicant should submit the program for approval prior to submitting it as part of the Maintenance Application process.

EXAMPLES OF ACCEPTABLE PROVIDERS OF ACCREDITED PROFESSIONAL DEVELOPMENT CONTACT HOURS:



- ACRP
- All state and national nursing associations (e.g. ANCC, CBRN)
- Accreditation Council for Pharmacy Education (ACPE)
- Accreditation Council for Continuing Medical Education (ACCME) (e.g. CME and AMA Category I credits)
- Other national healthcare-related associations offering professional development contact hours
- College/university courses in healthcare and clinical research
- Regulator-sponsored educational programs
- In-company training on research topics with specific learning objectives awarding a certificate/proof of attendance and specifying the number of hours (SOP training is not acceptable.)

CONTINUING INVOLVEMENT

Continuing Involvement is another area in which a candidate for Maintenance can earn points toward the stated Maintenance requirements. These are activities other than attending a professional development educational activity.

<u>Continuing Involvement Activities</u>			
<i>CCRC /CCRA/ CCTI applicants may document up to 12 points in this category from activities listed below. These points DO NOT satisfy the required points from participation in research-related professional development programs</i>			
Continuing Involvement (CI) Activity	Number of Points Awarded Per Activity	Maximum Points Allowed in this Category	Examples of Documentation Required for Verification <i>(CI activities are required to be included on the online Contact History Report or the Academy's Activity form)</i>
Professional development developer or presenter in clinical research or related topic <i>(to both research and non-research audiences)</i>	2	8	Copy of program with speakers and objectives or presentation abstract including organization, location and dates <i>(this is not required for speakers at ACRP's Global Conference)</i>
Authorship of journal paper on clinical research <i>(cannot be self-published)</i>	2	8	Journal citation including Authors



**ACADEMY OF CLINICAL
RESEARCH PROFESSIONALS**

The Academy of Clinical Research Professionals (The Academy) is an affiliate of the Association of Clinical Research Professionals (ACRP).

Participate in or present at investigator meeting (<i>in-person or virtual</i>) or an initiation visit, if in lieu of an investigator meeting	2	4	Documentation of meeting date, time and proof of participation/presentation
Active Participation in a Regulatory Meeting (<i>does not include an audit</i>)	2	4	Proof of attendance
Involvement in a New Marketing Application Process (<i>specifically compiling a specific section or writing a clinical study report</i>)	2	4	Supervisor documentation of role in specifically compiling a specific section or writing a clinical study report
Authorship of protocol (<i>sole or co-authorship</i>)	2	4	Supervisor documentation of role
Inclusion on 1572 or equivalent regulatory authority document as an active investigator or sub-I	2	4	Copy of 1572 (both sides) or equivalent regulatory authority document
Service as a peer reviewer of scientific articles	4 per 12-months of service	8	Confirmation of appointment as a peer reviewer that includes dates
Service as a peer reviewer of clinical-research related papers or of clinical research grants	4 per 12-months of service	8	Confirmation of appointment as a peer reviewer that includes dates
Service on IDMC/DSMB or equivalent	4 per 12-months of service	8	Letter from DSMB/IDMC chair outlining level of participation and # of mtgs attended
Volunteer Service on IRB/IEC	4 per 12-months of service	8	Letter from IRB chair outlining level of participation and # of mtgs attended
Service on healthcare-related exam committee	4 per 12-months of service	8	Proof of participation



Service as a clinical research exam item writer	0.5 points per question submitted	12	Proof of participation
Service on an association's clinical research-related committee (<i>editorial board, conference session review, regulatory affairs are permitted. Membership, nominating, general board service not permitted</i>)	4 per 12-months of service	8	Proof of participation
<i>Other activities may be approved on a case-by-case basis by the Academy Board.</i>			

- ***Presentation Development and Delivery:*** A single presentation can be claimed only once per year. The same presentation can be counted a second time the following year only if the presentation required significant updates prior to being presented again.
 - Certificants are permitted to include presentations they were paid to develop and present to the extent allowed by the above chart. Certificants cannot claim participation points for programs that they present.
- ***Authorship*** of an article pertaining to Clinical Research
 - Certificants are not required to be the primary author to be able to claim points for a published article.
 - An article must be published within the appropriate time frame for the current *Maintenance* cycle.

Presentations and articles must be in clinical research-related topics in order to be considered for points.

TAKING THE EXAM FOR MAINTENANCE

Taking and passing the current form of the exam for a specific designation's Maintenance is acceptable and satisfies all point requirements (all 24 points). The exam must be taken and passed BEFORE the candidate's Certification expires. A candidate must then submit a copy of their score report with their Maintenance application. This would include taking another Academy Certification exam to obtain an additional credential (i.e., a CCRC taking the CCRA exam in order to also achieve the CCRA designation.)

When being used for Maintenance, candidates are expected to apply for the exam, using the Examination for Maintenance Form in accordance with the regular exam window deadlines. Once they are successful on the exam, a candidate must then apply for Maintenance in accordance with the regular process and deadlines and submit a copy of his/her score report.



If a candidate wishes to use the exam for another Academy designation, as in the example above, for Maintenance he or she must still apply for and be deemed eligible for that program. In this instance, the Examination for Maintenance Form cannot be used.

If a candidate is unsuccessful on the examination, he or she may still submit the necessary 24 points to satisfy the Maintenance requirements.

NON-COMPLIANCE OF THE MAINTENANCE REQUIREMENTS

Candidates for Maintenance are expected to submit an application for Maintenance that fulfills all the necessary requirements no later than his/her certification expiration date. A candidate will be considered non-compliant if:

- no application for Maintenance was submitted;
- if the application submitted does not meet the stipulated requirements and the candidate has not rectified any deficiencies; or
- if randomly selected, the candidate has not satisfied the requirements of the Document Verification Process.

If compliance is not achieved within the stipulated timeframe, the candidate's certification will expire and the designation will be permanently removed from his/her record. The individual must stop using the designation and/or representing him or herself as certified.

Once a candidate's certification has been removed from his/her record, the only way to regain use of the credential is to apply to the program as a candidate for initial certification and to take and pass the current form of the examination.

