ACADEMY OF CLINICAL RESEARCH PROFESSIONALS

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

Academy of Clinical Research Professionals
Policy on Continuing Competency and Maintenance for the CPI 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 CPIs continue to:

- obtain current professional development information;
- explore new knowledge in specific content areas;
- master new clinical research-related skills and techniques;
- enhances 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 for CPI Maintenance must submit 24 points as part of the Maintenance application. The point requirements are broken down below. At least eight (8) of those 24 points must come from participation in research-related professional development programs AND at least twelve (12) of those 24 points must come from Continuing Involvement activities.

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Maintenance of Certification– Two Options			
	Participation in Professional Development	**Continuing Involvement Points** *(see chart)*	**Total Points Required**
Option 1 - Points	***At least* 12 points total** ***At least* 8 points from Research topics** ***No more than* 4 points from Disease/Bodily Systems/Other Healthcare topics**	***At least* 12 points total**	**24**
OR			
Option 2 - Examination	Pass the current form of the CPI exam prior to your *Certification* expiration date		
ALL Applicants **Copy of current medical license is required to be submitted with Maintenance application.**			

CPIs must submit at least eight (8) points of research-related professional development program.

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

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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

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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.

Professional Development Activities *All applicants MUST document 12 points in this category from activities listed below*			
Activity	**Time Spent**	**Contact Hours**	**Points on *Maintenance* Application**
Professional Development Session *(non-accredited programs)*	< 45 minutes 45-60 minutes 90 minutes	No points awarded 1 contact hour 1.5 contact hours	0 points 1 contact hour = 1 point 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

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- 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

In addition, CPIs MUST submit at least 12 points from the Continuing Involvement Chart. This is because some PIs do not do research full-time. Requiring the Continuing Involvement points is a way of making sure that they are still involved in clinical research in a meaningful way. These are activities other than attending a professional development educational activity.

Continuing Involvement Activities *All applicants MUST document 12 points in this category from activities listed below*			
Continuing Involvement (CI) Activity	**Number of Points Awarded Per Activity**	**Maximum Points Allowed in this Category**	**Examples of Documentation Required for Verification** *(CI activities are required to be included on the online Contact History Report or the Academy's Activity form)*
Professional development developer or presenter in clinical research or related topic *(to both research and non-research audiences)*	2	8	Copy of program with speakers and objectives or presentation abstract including organization, location and dates *(this is not required for speakers at ACRP's Global Conference)*
Participate in or present at investigator meeting *(in-person or virtual)* or an initiation visit if attended in lieu of an investigator meeting	2	4	Documentation of meeting date, time and proof of participation/presentation
Participate in a close out visit	1	3	Report signature page
Active Participation in a Regulatory Authority meeting *(does not include an audit)*	2	4	Proof of Attendance
Authorship of journal paper on clinical research *(cannot be self-published)*	2	8	Journal citation including authors
Authorship of journal paper on a therapeutic topic *(cannot be self-published)*	2	8	Journal citation including authors

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Authorship of protocol *(sole or co-authorship)*	2	4	Supervisor documentation of role
Authorship/review of clinical study report *(sole or co-authorship)*	2	4	Report signature page that includes protocol # or study name
Inclusion on 1572 or equivalent regulatory authority document as active investigator or sub-I	2	6	Copy of 1572 (both sides) or equivalent regulatory authority document
Medical monitor for clinical research trial	1	3	Name listed on protocol title page (sponsor)
Clinical research compliance officer for institution	12 per year	12	Copy of appointment letter
Director of research center	12 per year	12	Copy of appointment letter
Involvement in a New Marketing Application process *(specifically compiling a section or writing a clinical study report*	2	4	Supervisor documentation of specifically compiling a specific section or writing a clinical study report (signature page or supervisor letter confirming role)
Investigational New Drug or Device Application / Clinical Trial Exemption Application	2	4	Supervisor documentation of authoring the application (signature page; supervisor letter confirming role)
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 clinical research grants	4 per 12-months of service	8	Confirmation of appointment as a peer reviewer that includes dates
Service on DSMB/IDMC 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/IEC chair outlining level of participation and # of mtgs attended
Service on healthcare-related exam committee	4 per year of service	8	Copy of certificate/proof of participation
Service as a clinical research exam item writing writer	0.5 points per question	12	Proof of participation

	submitted		
Service on an association's clinical research-related committee (Editorial Advisory Board, conference session review, regulatory affairs committee is permitted. Membership, nominating or general board service not permitted)	4 per year of service	8	Proof of participation
Other activities may be approved by the Academy Board on a case-by-case basis			

- *Professional Development 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

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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.