



Certification Handbook

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APPLYING FOR CERTIFICATION

Welcome and Congratulations

The Academy of Clinical Research Professionals (the Academy) would like to congratulate you on your decision to pursue certification in your chosen field of work. As a professional in clinical research, you deserve to be recognized and appreciated for what you do, and like most professionals, you want to become better at it. You look for opportunities for ongoing professional development and practical ways to evaluate your own work that will help you develop as a professional.

ACRP Certification Overview

In order to achieve certification, all applicants must meet the eligibility requirements and pass an exam. Exams are administered twice annually, Spring and Fall, at over 600 testing centers in more than 80 counties.

The applicant should determine his/her own eligibility before submitting an application to the program. Upon submission of a complete application, an eligibility review is conducted by the Academy. The candidate is then notified of the eligibility review outcome via e-mail. All eligible candidates must then schedule an appointment to take the exam.

Candidates who meet the eligibility requirements and pass the exam will be certified as having met the Academy standards for becoming an ACRP-Certified Professional (ACRP-CP). Maintenance of one's certification is required every two (2) years.

Application Deadline

All application materials, including application, CV or resume, job description(s) and payment must be received by August 14, 2017 for the September/October examination. Applications received by June 14, 2017 qualify for the Early Bird rate.

Confidentiality

Application for, and achievement of, certification is between the Academy and an individual candidate. Therefore, ALL application, eligibility, and exam details are confidential to the individual and cannot be disclosed, regardless of payer. Only the <u>candidate</u> is permitted to withdraw an application or cancel an exam appointment, regardless of payer.

Application Process and Requirements

Professional Level Experience Requirements

To be eligible for the examination, an applicant must have the required minimum number of hours in the professional practice of clinical research. Internship (paid or unpaid) or volunteer experiences will not count toward the hours requirement.

NOTE: ACRP reserves the right to request backup documentation to substantiate the reported information at any time during the application process and/or once the candidate has been certified.

ACRP-CP Eligibility Requirements

As defined by the Academy, and determined through ACRP's 2017 Job Analysis Survey, in order to be deemed eligible to take the ACRP-CP exam, applicants must be able to provide evidence through a detailed job description, detailed CV, or other documentation that they are involved in at least one of the following:

- Planning protocol design, feasibility assessment, business operations (budgeting, contracting, billing compliance), site selection activities, regulatory document preparation, collection, and/or submission, site management activities, clinical operations role within site, academic medical centers or CROs.
- Conducting conduct of clinical trials with participants
- Overseeing (management, administration) study site management (Site, CRO, Sponsor, monitoring activities (including in-house, central and remote monitoring), project management, quality control, quality assurance, data management, medical monitoring, safety monitoring (medical safety liaison, pharmacovigilance, IRB professional).

Hours performing the requirements for the ACRP-CP certification **can include hours** documented up to the date of the exam and/or through previous employment. The required number of hours is dependent upon one's educational background. See below:

| Α | ACRP-CP Eligibil | ity Requirements met <u>before applying</u> fo | |
|----------|---|--|--|
| | Education | Minimum Hours Performing Essential Duties | Required Documentation of Performed Essential Duties |
| Option 1 | Bachelor's Degree (or higher) | 3,000 hours* | Detailed CV/résumé <i>and</i> Job Description |

| Option 2 | Associate's Degree ORLPN, LVN, RN | 4,500 hours* | Detailed CV/Résumé and Job Description |
|----------|--|--------------|---|
| Option 3 | High School Diploma ORMedical Assistant or Lab Technician | 6,000 hours* | Detailed CV/Résumé and Job Description |

^{*}see section for options of substitutions for work experience

Substitution for Work Experience Requirements

Applicants may only choose one option below as a valid substitute. Under no circumstance will an applicant be permitted to use more than one substitution for the same application.

Clinical Research Certifications (Option 1)

ACRP acknowledges that there is a shared knowledge base between CCRA, CCRC, and CPI designation holders and those who seek the ACRP-CP designation. Any candidate for the ACRP-CP designation who has a current CCRA, CCRC, or CPI designation will have achieved a valid substitute for 1,500 hours of the required professional experience for the ACRP-CP exam.

Clinical Research Education Programs (Option 2)

The Academy considers applicants who have completed a clinical research education program that meets the following standards to have achieved a valid substitute for 1,500 hours of professional experience for the ACRP-CP program.

Acceptable programs must:

- Be at least 216 contact hours in length (at least 15 semester credits) and;
- Cover content that substantially maps to the topics found on the **Detailed Content Outline** (DCO) and;
- Be accredited by an accrediting agency recognized by the Council on Higher Education Accreditation (CHEA) or the appropriate authorizing authority in the country in which the institution operations. A list of recognized US accrediting agencies can be found from the CHEA website: www.chea.org.

If an applicant opts to use an educational program as a substitute, he or she may send an email to certification@acrptnet.org for additional requirement details.

Application and Exam Fees

The cost to apply includes an exam and application fee, paid together at the submission of the application. Credit card, check, or bank transfers are acceptable forms of payment. The fees are as follows:

| | Member | Non-Member |
|-----------------------|-----------------------|-----------------------|
| EARLY BIRD DATES | \$135 application fee | \$135 application fee |
| May 1 – June 14, 2017 | \$300 exam fee | \$350 exam fee |
| | Total - \$435 | Total - \$485 |

| REGULAR DATES |
|----------------------------|
| June 15, 2017 – August 14, |
| 2017 |

| Member | Non-Member |
|-----------------------|-----------------------|
| \$135 application fee | \$200 application fee |
| \$325 exam fee | \$400 exam fee |
| Total - \$460 | Total - \$600 |

The application fee is non-refundable regardless of eligibility status or cancellation. Submission of the application confirms your understanding and agreement.

All Non-Members who apply will receive *one free year of ACRP Membership* upon successful passing of the exam.

Application for Certification

Once an applicant has carefully self-determined he/she meets the eligibility requirements, the application process can begin. Applications are submitted via a printable method such as fax or mail.

The following must be submitted together by the due date (*received, not postmarked*) to be considered for review of eligibility:

- 1. Application Form **AND**
- 2. Supporting documents—curriculum vitae (CV)/ résumé AND
- 3. Detailed job description(s)* for positions listed on the CV/ résumé AND
- 4. Full payment

All documentation must be provided in English. If the original documentation was translated into English, it must also be submitted in the original language, with the certified translated document.

Services for People with Disabilities

The Academy is committed to ensuring that no individual with a disability is deprived of the opportunity to take an exam solely by reason of that disability. The Academy will provide reasonable accommodations for candidates with disabilities pursuant to the Americans with Disabilities Act (ADA). The following reasonable accommodations may be addressed:

- Wheelchair access is available at all established test centers.
- Candidates with visual, sensory, cognitive, or physical disabilities that would prevent them from taking an exam under standard conditions may request reasonable accommodations and arrangements.

To request a reasonable accommodation, one is required to check the designated box on the exam application and also submit:

Special Accommodations Form, signed by a licensed health professional approving the request as accurate and reasonable. This MUST be submitted at the time of application.

^{*}If you cannot obtain a job description from your (former) employer, you may create and supply your own. If necessary, you may email certification@acrpnet.org for a sample CV or job description.

Completing the Application Form

There are two ways candidates can complete their applications: online (recommended) or a printable version*. Both versions are accessible on the <u>Certification Resources</u> web page. Copies are not available for print so it is recommended to take screen shots, if and as needed.

Note: The application will time out within five minutes of inactivity. Therefore, it is imperative to have all documentation and information ready so that data in the online application is captured and not lost.

*If paying by check or bank transfer, applicants must submit the <u>printable version</u> of the application. Be sure to include the check or receipt of bank transfer with the application.

Submitting the Application

Only applications received with required supporting documentation and full payment will be processed. File sizes must be less than five (5) megabytes for online applications.

Note: Incomplete applications, or applications submitted without the correct fee, will not be considered. It is the candidate's responsibility to submit all relevant documents and payment at the time of application, by the due date.

Submission of the application constitutes agreement that the candidate has read, understood, and agrees to abide by the <u>ACRP Code of Ethics and Professional Conduct</u>. Applicants are required to sign a Candidate Statement of Authorization and Agreement attesting to the accuracy of the information provided as part of the application process. By submitting an application, the applicant consents to and authorizes the Academy to verify the candidate's academic and employment records.

Receipt of Application

An e-mail confirmation of payment is automatically sent once payment is processed. At that point, applications will enter the Eligibility Review process.

THE ELIGIBILITY REVIEW PROCESS

Eligibility Review

The eligibility review process includes determining completeness of the application and whether or not the applicant meets the eligibility criteria for the exam and performs all essential duties. Applicants should expect to receive an update on application status (via email) within seven to ten days after the application has been received.

Applicants will have seven (7) calendar days to respond to any request for additional information from an eligibility reviewer. These requests will only come via e-mail.

Incomplete Applications

Applicants who do not respond to the requests for additional or clarifying information will automatically have their applications determined incomplete and therefore will be found ineligible to take the exam.

Eligibility Reviewers

An applicant may receive a request for additional and/or clarifying information from a reviewer in support of his or her application. This is not unusual or uncommon. Reviewers only communicate via email and are not available to speak with an applicant via phone concerning his or her application. Therefore, it is imperative that an applicant contact ACRP in the event communication about the review outcome has not been received through email.

Confirmation of Eligibility

Upon conclusion of review, an applicant will be found to be: eligible or ineligible.

Eligible applicants will be e-mailed an Eligibility Notice, with instructions as to how to schedule an exam appointment. Exam appointments can only be scheduled *after* eligibility is determined.

Ineligible applicants *automatically* receive up to two levels of review. Applicants are notified via e-mail at each step of the review with an explanation of the deficiency identified. Each level of review can take up to seven days. If after two reviews and the applicant is found Ineligible, a review will be conducted by the Certification Manager and the applicant will be notified via email with the final result.

Ineligible applicants (who do not initiate the appeals process* within 15 days of notice) will be refunded the exam fee and will need to re-apply and pay all fees if they decide to pursue certification in the future.

*If the applicant is still determined to be ineligible after three levels of review, the applicant can choose to appeal to the Academy Board of Trustees. However after the third review, applicants can no longer submit new documents to overturn an eligibility decision.

View the Academy's Policy on Appeals.

ACRP-CPI EXAMINATION INFORMATION

Exam Structure

The ACRP-CP Exam is designed as a practice-based exam to assess proficiency of the six (6) core knowledge areas:

- 1. Ethical and Participant Safety Considerations
- 2. Investigational Product/Device Regulation
- 3. Clinical Trial Operations (GCPs)
- 4. Study and Site Management
- 5. Scientific Concepts and Research Design
- 6. Data Management and Informatics

Exam Delivery

The ACRP exam consists of 125 multiple-choice questions (25 of these questions are pre-test items, do not affect a candidate's score and are not identified to candidates). Each candidate is allowed a maximum of three (3) hours to complete the 125 questions. Candidates are presented with a question and are asked to choose the single **best** answer from the four options provided. Only one answer is correct. There are no "trick" questions on the exam and there is no penalty for guessing.

Language

The exam is provided in English.

Exam candidates may bring a hard-copy, **translation only** (word-to-word) dictionary to the exam. Electronic dictionaries are not permitted. Dictionaries containing any word definitions or other extraneous markings are strictly prohibited. The dictionary will be inspected by the proctor before and after the exam is completed. No additional time is given to those using a translation dictionary.

Exam Administration

The Academy partners with Prometric, a trusted provider of technology-enabled testing, to administer its exams. Once a candidate has been found eligible, coordination of scheduling (including confirming, rescheduling or canceling) his or her exam will occur directly through or with Prometric via online or phone.

Examination Window

The candidate must test during the window for which he or she is approved. The Academy offers its exams each year during two testing windows, March and September. The Fall 2017 testing window begins September 8, 2017 and concludes October 7, 2017. *Candidates will not be permitted to schedule an appointment outside of this testing window under any circumstances*.

Exam Appointment Scheduling

The exams are administered via a secure network of computer-based testing sites. Over 600 locations in more than 80 countries are available at which to take the exam. All candidates who have been found eligible <u>must</u> schedule an appointment to take the exam. **Candidates who do not schedule an exam risk forfeiting all fees.**

Appointments can be scheduled online (recommended) or by phone. To view testing locations, visit www.prometric.com/acrp at any time.

Confirmation Number

When a candidate schedule his or her appointment, a confirmation number will be provided. Make sure to keep a record of your confirmation number and appointment information. You will need your confirmation number if you want to confirm, reschedule, or cancel your appointment with Prometric.

Confirming Your Appointment

It is the responsibility of a candidate to verify that they have been scheduled for the date, time, and place he or she has requested. One may confirm his or her appointment in two ways:

- Confirm an appointment online at www.prometric.com/ACRP
- Call (800) 967-1139 or the applicable <u>international number</u> and select the option for confirming your appointment

An appointment can be confirmed online even if scheduled via phone.

Rescheduling Your Appointment

Rescheduling an exam appointment is permitted by Prometric up to five (5) days BEFORE your scheduled appointment. There may be fees associated with appointment changes. Rescheduling availability may vary, depending on the test center location and number of days prior to the exam appointment date.

Candidates *must* contact Prometric directly to reschedule an exam appointment. ACRP cannot reschedule your appointment. You may reschedule by phone or online and the appointment confirmation number will be needed.

Cancellations, No Shows, Re-Examination, Refunds and Transfers

Cancellations

Candidates who wish to cancel their application may submit an <u>Application Cancellation Request Form</u> to obtain a refund of the exam fee **only**. The application fee covers costs associated with reviewing the application and <u>is non-refundable</u>.

Emergency Cancellations

Candidate unable to keep their exam appointment due to an emergency situation within five (5) days of the exam date, must submit an Emergency Cancellation Form and official documentation to certification@acrpnet.org. This information may be received up to seven (7) calendar days after the candidate's scheduled exam date.

The following situations will be considered with documentation: Emergency room visit or hospitalization, severe medical condition requiring hospitalization, death of an immediate family member (e.g., spouse, child/dependent, parent, grandparent, sibling), call to active military duty, or jury duty.

No Shows and Missed Exams

If a candidate schedules an exam appointment and fails to take the exam, he or she forfeits all fees. If a candidate arrives late for a scheduled exam appointment, he or she may not be allowed to test and, subsequently, will not be eligible for a refund. Missed exams due to lateness are not eligible for a refund.

Re-Examination

Candidates who do not pass the certification exam on first attempt will be allowed to re-take the exam ONLY in the next examination period. A "Re-Examination Form" will be included with the official exam results confirmation letter.

Refunds

Refundable fee: examination fee only.

The application fee covers the cost associated with reviewing the application and therefore <u>is non-refundable</u>.

No one other than the candidate may request a cancellation or refund. Refunds are issued to candidates under two circumstances only: **ineligibility** or **cancellation**.

Ineligibility

Ineligible applicants will receive a refund of the exam fee, within three weeks of the final ineligibility notification.

Cancellation

To receive a refund, the cancellation request must be received at least five (5) calendar days **BEFORE** an exam appointment. Requests within five days of an exam appointment will not be honored.

Refunds are *not* available to candidates who do not schedule or attend the exam.

Refunds will be sent to the party who initially paid for the exam. If payment was made by credit card, that card will receive the credit. If that card is no longer valid, a check will be mailed. If the payment was made by check, the Academy will mail a refund check to the original payer.

Transfers

The Academy offers a **one-time** transfer from the current exam offering to the next. There are two situations in which candidates may take advantage of this:

- 1. If a candidate is determined **ineligible** for the current exam window, but will have met the eligibility requirements by the next exam window; or
- 2. If an **eligible** candidate withdraws from taking the original exam for any reason (up to five [5] days before a scheduled exam appointment)

Transfers are applied toward the next exam **only**. Transfer of eligibility and associated fees will be applied only to the original candidate and are not transferable to another person, even if paid for by a third party. Exam fees are transferred toward the next exam **only** and not toward other products or services.

If you choose to transfer to the next exam window for one of the two reasons above, you must submit a Request to Transfer Exam Application Form before the end of the exam window for which you had originally applied.

If you have an exam appointment scheduled, you must **first cancel** it directly with Prometric before submitting the <u>Request to Transfer Exam Application Form</u> to ACRP. Fees, payable to Prometric directly, apply for appointment cancellations made within thirty (30) to five (5) days prior to an appointment date. Cancellations are not permitted less than five (5) days prior to an appointment.

If a transfer candidate does not submit the request before the end of the current exam testing window, then all funds originally submitted will be forfeited. Transferring is not an option for re-examination candidates (from the previous exam cycle).

When a transfer request has been approved, all fees (application and exam fees) are applied automatically at the start of the next application period. All **eligible** transfer candidates will receive an email notice of Eligibility when the Eligibility ID has been reactivated and an exam appointment can be scheduled. Contact **certification@acrpnet.org** if you did not receive your new Eligibility notice. Candidates who are required to submit documentation for subsequent eligibility review must do so at the start of the next application period.

View full Policy on Transfers, Cancellation, No Shows, Refunds and Re-Examination

Preparing for the Exam

The best preparation is to understand the ACRP-CP knowledge requirements and their application to clinical research. You might want to review the *Detailed Content Outline* for topics or subtopics with which you are less familiar. If you find a particular area with which you are not familiar or comfortable, that would be an area on which to focus your study or review. Or, you may want to do a surface review of all the content areas, even those you believe you know well.

Because of the nature of the exam, there is not one comprehensive source to go to in order to study. However, the Academy does recommend that you review the content areas covered on the exam by using the Detailed Content Outline.

What's Covered on the Exam?

Detailed Content Outline

The DCO is derived from the 2017 ACRP Job Analysis Survey, a careful description of the tasks performed by an ACRP-CP candidate. Each question on the exam is based on this outline. Therefore, to prepare to take the exam, one should study this outline and especially consider the underlying knowledge, skills, and abilities needed to perform in his/ her role as a Certified Professional.

Study Texts

ICH Guidelines
Declaration of Helsinki

Preparation Support

Certification Abbreviation List

The Abbreviations List contains abbreviations that may be used throughout the exam and exam Detailed Content Outline. The abbreviations list is accessible on each screen during the exam and can be found on our <u>website</u>.

<u>IMPORTANT</u>: The Academy **DOES NOT** sponsor or endorse any specific educational courses; even if the course is advertised as a "prep" or "review" course for the exam. Those creating the course **do not have ANY** inside information about the exam. Participation in these courses may help you learn or review topics covered on the exam, **but you should not expect them to directly cover exam content**. The same information that is included in this handbook to help you prepare is publicly available to those creating educational content.

Taking the Exam

It is important for candidates to understand their rights and responsibilities in the secure testing environment of the Prometric test center. It is recommended that you review the full Policy on Testing Experience Issues.

Exam Appointment Arrival

It is the candidate's responsibility to arrive on time for the exam appointment. If the candidate is late by 15 minutes or more, the test center has the authority to turn the candidate away and not permit the candidate to take the test. Plan to arrive 30 minutes before your appointment. If you miss your scheduled exam appointment for any non-emergency reason (lack of child care, lateness due to work or traffic, etc.) your opportunity to test will be lost.

Required Identification

To access a secure testing center you must present proper identification (ID) containing your legal name. Examples of proper ID include a passport, driver's license, state or government-issued ID.

Your legal name MUST match the **first name** and **last name** listed on your Eligibility Notice (emailed from ACRP) and on the Appointment Confirmation (from Prometric). Middle names are excluded. Your ID must meet **each** of the following criteria:

| government-issued AND |
|---------------------------------------|
| current (non-expired) AND |
| photo-bearing AND |
| signature-bearing identification (ID) |

The photo must look like the examinee. Signature on ID must match the signature provided during the sign-in process. Major discrepancies will result in a candidate being denied from the testing center and result in forfeiture of all fees paid.

If the name listed with ACRP and Prometric is not your legal name, you must submit a <u>Name Change</u> <u>Request</u> to <u>certification@acrpnet.org</u> immediately.

Exam Security and Test Center Guidelines

Prometric is serious about test center security. You will be presented with Prometric Test Center
Regulations upon arrival at the test site. Those who violate security will not have their exams scored or processed, and will be required to leave immediately. Attempting to remove exam material or content from the test center will result in severe consequences.

Once seated, you will follow a brief on-screen tutorial for navigating through the exam. Your exam will begin after the tutorial. Each exam will be delivered via individual video-monitored testing carrels. Immediately raise your hand at any time if your computer or any provided resources are not functioning properly!

What Not to Bring: Any and all personal items will be locked in a locker. Examples include a purse, keys, wallet, calculators, watch, cell phone, all electronic devices, tissues, outerwear (heavy coats), food, and all books and papers.

Attire: Prometric <u>will not</u> allow you to remove any article of clothing (headbands, jewelry, scarves, shoes, light sweaters, etc.) that you wear into the room. Whatever you choose to wear, please plan to wear the entire length of the exam.

Resources Available at the Test Center

The following resources will be available, issued only by the test center:

- An abbreviations list is also available on screen
- Hand-held calculator (an on-screen calculator is also available)
- Noise cancelling head set
- White board and dry-erase markers

Exam Scores

The passing scaled score for the exam is 600. A candidate scoring below 600 has not been successful on the exam and cannot be certified.

One point is granted for each correct answer. There is no penalty assessed for an incorrect answer. The number of questions answered correctly (or total points) is a candidate's "raw score." Prometric then converts a candidate's raw score to a scaled score. The "Total Scaled Score" will determine whether a candidate has passed the exam. The exam is not scored on a curve and there is no predetermined number of candidates permitted to pass. Your score does not depend on the other candidates testing with you that day.

Note: The passing point set for the exam cannot be appealed.

Specific questions on the exam and/or answers to exam questions will not be discussed or released. Due to the security of the item bank and because exam questions can be used on various exams, exam questions will not be discussed with candidates and candidates may not have access to the exam or their answers.

Note: For more information on scaled scoring, please contact us at certification@acrpnet.org.

Exam Results and Notification

Computer-based testing immediately provides participants with preliminary results. You will receive a printed proficiency assessment before you leave the test center. You will receive official confirmation of your certification status via email and postal mail, approximately 30 days following the close of the testing window.

Candidates, are not yet considered certified until *official* notification of certification status is received from the Academy.

Candidates who pass the exam will be sent an official letter, a certificate, a certification pin, and Maintenance of Certification information. They will also be added to the Academy Certification registry unless this option was de-selected at the time of application. The registry will be updated within 30 days following the close of the testing window and can be accessed at www.avectraacrp.com/Certlist.

Candidates who do not pass the exam are advised to review the content area proficiency ratings and use this information to assist in preparing for future exams. Final exam results will **not** be given out over the telephone or by fax, nor will results be sent to employers, schools, other individuals, or organizations under any circumstances.