

ACRP CERTIFICATION HANDBOOK

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APPLYING FOR CERTIFICATION

Welcome and Congratulations

ACRP 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 countries.

The applicant must determine their own eligibility before applying to the program. Upon submission of a complete application, an eligibility review will be conducted by ACRP. 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. Maintenance of one's certification is required every two (2) years.

Application Deadline

All application materials, including the completed application, CV or resume, and payment must be received by March 31, 2022 for the spring testing window, February 15, 2022 – April 15, 2022. Applications received from October 18, 2021 – December 31, 2021 qualify for the Early-Bird rate.

Confidentiality

Application for, and achievement of, certification is between ACRP 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 candidate 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 a minimum of 3,000 hours of experience in the professional practice of clinical research. Internship (paid or unpaid), volunteer experiences, and hours earned through educational programs will not count toward the experience 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.

Eligibility Requirements

In order to be deemed eligible for an ACRP Certification exam, applicants must attest to having earned 3,000 hours of experience performing the knowledge and tasks located in the Detailed Content Outline of the designation they are applying for. Any experience older than ten years will not qualify.

- <u>ACRP-CP Detailed Content Outline (DCO)</u>
- <u>CCRA Detailed Content Outline (DCO)</u>
- <u>CCRC Detailed Content Outline (DCO)</u>
- <u>CPI Detailed Content Outline (DCO)</u>
- DCO)provide proof of employment as a PI orDCO)Sub-I on at least two studies.CO)

Candidates for the CPI exam must

Applicants for the ACRP-PM or ACRP-MDP subspecialty designations must hold an active ACRP-CP, CCRC, CCRA, or CPI at the time they apply in order the qualify.

- <u>ACRP-PM Detailed Content Outline (DCO)</u>
- <u>ACRP-MDP Detailed Content Outline (DCO)</u>

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.

ACRP Certifications (Option 1)

ACRP acknowledges that there is a shared knowledge base between ACRP-CP, CCRC, CCRA, and CPI certificants. Any candidate who is actively certified with ACRP at the time that they apply will earn a 1,500-hour substitute of the required 3,000 hours of professional experience.

Clinical Research Education Programs (Option 2)

ACRP considers applicants who have earned a clinical research degree from an institution accredited by the <u>Council on Higher Education Accreditation (CHEA)</u> will earn a 1,500-hour substitute of the required 3,000 hours of professional experience.

Applicants for the CPI program will receive a waiver for one (1) of the two (2) required studies.

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 May 15, 2022 – July 15, 2022	\$135 application fee	\$135 application fee
	\$300 exam fee	\$350 exam fee
	Total - \$435	Total - \$485
	Member	Non-Member
REGULAR DATES July 16, 2022 – September 30, 2022	\$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. Additionally, if the applicant wishes to switch program types after applying, they will be charged an additional application fee.

Application for Certification

Once an applicant has self-determined they meet the eligibility requirements, the application process can begin. To apply, candidates must:

- 1. Log in to their ACRP account or create one online at <u>www.acrpnet.org</u>
- 2. Go to their account and click on *My Profile*
- 3. Select the link on the right-hand side that says Apply for Certification

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 translated document.

Submitting the Application

The application process is only offered online. The applicant will have the ability to start and save it prior to submitting.

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 ACRP 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.

Services for People with Disabilities

ACRP 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. ACRP 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 application and also submit:

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

THE ELIGIBILITY REVIEW PROCESS

Eligibility Review

The eligibility review process is a random audit which includes determining completeness of the application and whether the applicant meets the eligibility criteria for the exam. 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 Ineligible and therefore will not be able to take the exam.

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 Director 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 ACRP's Policy on Appeals.

EXAMINATION INFORMATION

Exam Structure

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

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

Exam Delivery

The ACRP exam consists of 125 multiple-choice questions (25 of these questions are pre-test items and do not affect a candidate's score nor are they identified to the candidate). Each candidate is allowed a maximum of three (3) hours to complete the 125 questions. ACRP's subspecialty exams consist of 60 multiple choice questions (10 pre-test items) and candidates are alloted 90 minutes to complete their exam. 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-toword) 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

ACRP 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. ACRP offers its exams each year during two testing windows, spring and fall. The spring testing window begins February 15, 2022 and concludes on April 15, 2022. The fall testing window begins July 15, 2022 and concludes on October 15, 2022. *Candidates will not be permitted to schedule an appointment outside of the 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 schedules 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 <u>www.prometric.com/ACRP</u>
- Call (800) 967-1139 or the applicable <u>international number</u> and select the option for confirming your appointment

Rescheduling Your Appointment

Rescheduling or cancelling your appointment (test center location, date, or time) is permitted by Prometric up to five (5) days before your scheduled appointment. Candidates who make changes 16-29 days before a scheduled appointment will be charged a \$25 fee by Prometric; 5-15 days before a scheduled appointment, Prometric will charge a \$50 fee. Candidates who cancel less than 5 days prior will have to repay the examination fee in order to test. 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 <u>Emergency Cancellation Form</u> and official documentation to ACRP at <u>www.acrpnet.org/contact</u>. 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, 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

ACRP offers its examinations each year during two testing windows, Spring and Fall.

Candidates who do not achieve a passing score on the certification examination will only be allowed to re-take the exam during the next available examination period by submitting the examination fee.

If the candidate is not successful on this *"re-take"* examination, he or she will need to complete a new application and pay all fees in place at the time for any subsequent exams.

If a candidate chooses to transfer his or her first examination opportunity and, subsequently, does not pass, he or she will need to complete a new application, meet all eligibility criteria in effect at that time, and pay all fees in place at the time for any subsequent exams. Candidates who do not achieve a passing score on their second attempt or who are unable to test again during the next examination period must submit a new application, together with all current fees, to continue their pursuit of certification. Such reapplications will be subject to all eligibility criteria in effect at that time. This policy protects the security of the integrity of the examination by preventing item over-exposure. It is ACRP's policy to maintain two unique tests forms and update test items yearly to reduce any possible over exposure by candidates by following the six-month waiting period. The time period between testing windows also provides a sufficient amount of time for candidates to increase the amount of study or change their method of test preparation. Candidates will not be permitted to schedule an appointment outside of the testing windows under any circumstances.

Refunds

Refunds are issued to candidates who are ineligible or candidate who request a cancellation. The application fee covers the cost associated with reviewing the application and therefore is nonrefundable. The examination fee is fully refundable granted the candidates has:

- Has not taken the examination and;
- Provided a written request to ACRP and;
- Has cancelled their exam appointment with Prometric more than 5 days before the original appointment (if applicable)

No one other than the candidate may request a cancellation or refund.

Ineligibility

Ineligible applicants will receive a refund of the examination 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 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, ACRP will mail a refund check to the original payer.

Transfers

ACRP offers a **one-time** transfer from the current exam offering to the next for a \$50 fee. 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 <u>only</u> 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 before the end of the exam window for which you had originally applied. To submit a transfer request, you must access your online application and select *Request Exam Window Transfer*.

If you have an exam appointment scheduled, you must **first cancel** it directly with Prometric before submitting your online request to transfer to the next exam window. Fees, payable to Prometric directly, apply for appointment cancellations made within thirty (30) to five (5) days prior to an appointment date and do not include transfer fees paid to ACRP. 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 <u>www.acrpnet.org/contact</u> 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 exam is specific to the knowledge and tasks identified in the <u>Detailed Content Outline</u>. It requires a general working knowledge of the roles and responsibilities to perform in your role safely and effectively, with grounding in ICH GCP and the application of those guidelines.

The exam content expects that you will have a basic working knowledge of general laboratory terms, tests, and procedures, as well as how to perform basic math. It does not cover country-specific (FDA, EMA, etc.) regulations and does not test how your employer or you personally carry out those duties.

Candidates should 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, ACRP 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 (DCO)

The DCO is derived from an ACRP Job Analysis Survey, a careful description of the tasks performed by clinical research professionals. 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 clinical research coordinator.

Study Texts

All ACRP Certification exams are based on five ICH Guidelines and the Declaration of Helsinki:

- Guideline for Good Clinical Practice E6(R2);
- Definitions and Standards for Expedited Reporting E2A;
- General Considerations for Clinical Trials E8;
- Statistical Principles for Clinical Trials E9;
- Clinical Investigation of Medicinal Products in the Pediatric Population E11

ACRP-MDP examination only:

• ISO 14155:2011

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>.

Exam Practice Exercise

The Exam Practice Exercise, currently offered for the ACRP-CP, CCRC, CCRA, and CPI, is not intended to be a pre-test to determine a candidate's future success on the actual exam. Candidates should understand that this not considered a "practice test/exam". It is considered a practice exercise.

It functions to assist candidates in becoming more comfortable with the type of items on the exam. The exercise includes 50 retired items and provides the correct answer, the ICH Guideline reference that supports the correct answer, and a narrative explanation for the answer.

Additional Optional Support

ACRP provides optional exam preparation support which is available for purchase online, from <u>the Exam</u> <u>Preparation</u> webpage. There are options to purchase components separately or in a package. Visit the webpage for details and pricing for each option.

Further Study Tips

In addition to reviewing the DCO and ICH Guidelines, one way to review is to select texts and training materials you used when first taking on your role. You can select a publication that you may already have or borrow from a colleague. You should select books or publications that cover topics found on the Detailed Content Outline, the ICH Guidelines, or the tenets of GCP.

If you have time, take a workshop or attend a conference session on topics in which you need to become more familiar. **Any** professional development courses that cover clinical research topics will add to your knowledge base and therefore will help you prepare for the exam.

IMPORTANT: ACRP **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 <u>Policy on Testing</u> <u>Experience Issues</u>.

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 childcare, 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.

Please contact <u>www.acrpnet.org/contact</u> to submit any name change requests.

Exam Security and Test Center Guidelines

Prometric is serious about test center security. You will be presented with <u>Prometric Test Center</u> <u>Regulations</u> 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 headset
- 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.

For more information on scaled scoring, please contact www.acrpnet.org/contact.

Exam Results and Notification

The Score Report will be displayed at the end of the exam and emailed to the address that is provided to Prometric during the scheduling of the exam. It is a required field when scheduling both online and by phone. The email will also contain a link at the bottom that the candidate can click to Prometric's secured portal. The score report portal allows the candidate to log in with their appointment confirmation number, and their last name, to print out duplicates of their score report if needed, at any time. You will receive official confirmation of your certification status via email approximately three weeks after testing.

Candidates are not considered certified until *official* notification of certification status is received from ACRP.

Candidates who pass the exam will be have their ACRP account updated to reflect their certification status. A copy of the certification can be downloaded from the user's ACRP account. They will also have the option opt-in to ACRP's Certification registry so their certification status can be verified online. The

registry will be updated within 30 days following the close of the testing window and can be accessed at <u>https://acrpnet.org/certifications/verify-certification/</u>.

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 any future exam. 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.