ACRP

CERTIFIED CLINICAL RESEARCH COORDINATOR

Certification Handbook

Association of Clinical Research Professionals
99 Canal Center Plaza, Suite 200
Alexandria, VA 22314
acrpnet.org

Table of Contents

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 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 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 as having met ACRP's standards for becoming a CCRC. 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 17, 2018 for the September/October examination. Applications received by June 15, 2018 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 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.

CCRC Eligibility Requirements

In order to be deemed eligible to take the CRC Certification exam, applicants for the CCRC credential must be able to provide *evidence* through a job description, detailed CV or other documentation that they:

- Perform ***EACH*** of the CCRC Essential Duties as detailed below for a required minimum number of hours. Hours performing the CCRC Essential Duties **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.

CCRC Eligibility Requirements

At least one of the Eligibility Requirement options below should be met **before applying** for the CCRC program.

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

*see section for options of substitutions for work experience

CRC Essential Duties

As defined by ACRP, and determined through its 2015 Job Analysis Survey, clinical research coordinators who are eligible for CRC *Certification* must document cumulative performance of **each** of the following Essential Duties during the dates of employment listed on the application:

- Report and document safety issues (e.g. adverse events;)
- Participate in the preparation or review of documents exchanged with the institutional review board (IRB);
- Participate in protocol review or study procedures planning;
- Participate in conducting subject visits;
- Collect accurate, verifiable data, source documents, and essential documents;
- Prepare for and participate in sponsor audits and/or regulatory inspections, if applicable;
- Participate in the informed consent process.

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, CPI and ACRP-CP certificant holders and those who seek the CCRC designation. Any candidate for the CCRC designation who has a current CCRA, CPI or ACRP-CP designation will have achieved a valid substitute for 1,500 hours of the required professional experience performing the essential duties of a CRC.

Clinical Research Education Programs (Option 2)

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

Acceptable programs must:

- Be a completed Clinical Research Degree;
- Be accredited by an accrediting agency recognized by the Council on Higher Education Accreditation (CHEA) 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 May 1 – June 15, 2018	$135 application fee	$135 application fee
	$300 exam fee	$350 exam fee
	Total - $435	Total - $485

	Member	Non-Member
REGULAR DATES June 16 – August 17, 2018	$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.*

****If the applicant wishes to switch program type, they will be charged an additional application fee.***

Application for Certification

Once an applicant has carefully self-determined he/she meets the eligibility requirements, the application process can begin. Applications are submitted online.

If the applicant wishes to switch program type, they will be charged an additional application fee.

The following must be uploaded or submitted together by the due date 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

*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.

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

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 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.**

Submitting the Application

The application process is now available online. The applicant will have the ability to start and save it prior to submitting for formal review. Please note that all required documents must be included with application before payment can be processed online with a credit card.

If paying by check, complete and save the application online. As the website cannot process check payments online, please mail the check with your information clearly listed so that payment can be applied to your application for submittal.

Submission of the application constitutes agreement that the candidate has read, understood, and agrees to abide by the **ACRP Code of Ethics and Professional Conduct.** 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. 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 Ineligible and therefore will not be able to take the exam.

Eligibility Reviewers

Our Eligibility Reviewers are clinical research professionals hired by ACRP for the purpose of reviewing applications and determining eligibility. 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 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.**

CRC EXAMINATION INFORMATION

Exam Structure

The CRC 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 and 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, 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

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, March and September. The Fall 2018 testing window begins September 10, 2018 and concludes October 8, 2018. ***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 must 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 www.prometric.com/ACRP
- Call (800) 967-1139 or the applicable international number 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 Application Cancellation Request Form to obtain a refund of the exam fee **only**. The application fee covers costs associated with reviewing the application and is non-refundable**.**

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

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 a re-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
Refundable fee: examination fee only.
The application fee covers the cost associated with reviewing the application and therefore is non-refundable.

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, 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 ***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 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 **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 CRC exam is specific to the role that you play in the conduct of a clinical trial. 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.

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, 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?

The best preparation is to understand the CRC 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.

To be certified, CRCs, are expected to have *general knowledge* of: laboratory terminology, tests, and procedures; and basic math, including adding, subtracting, multiplying, dividing, and calculating percentages.

Detailed Content Outline
The DCO is derived from the 2015 ACRP Job Analysis Survey, a careful description of the tasks performed by clinical research coordinators. 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
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

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 website.

Exam Practice Exercise
The Exam Practice Exercise 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 also 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 the **Exam Preparation** 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 **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 **Name Change Request** to **certification@acrpnet.org** 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 **will not** 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.

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

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 and postal mail, approximately 30 days following the close of the testing window.

https://scorereports.prometric.com/

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

Candidates who pass the exam will be sent an official letter, a certificate, and Maintenance of Certification information within 30 days after the close of the testing window. They will also be added to ACRP's 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 that become certified will be able to showcase

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.

Appendix – CCRC Detailed Content Outline (DCO)

Certified Clinical Research Associate (CCRA®) Examination Detailed Content Outline

(Effective 1 January 2017)

This document contains the Detailed Content Outline (DCO) for the Clinical Research Associate Examination. Each question on the exam is based on this outline.

Introduction

The CCRA program is accredited by the National Commission for Certifying Agencies (NCCA®). NCCA Accreditation is an impartial, third-party validation that the CCRA program has met recognized national and international credentialing industry standards for development, implementation, and maintenance of certification programs. The Academy of Clinical Research Professionals (the Academy) develops the CCRA exam using certification industry best practices, as aligned with the NCCA Standards for Accreditation of Certification Programs.

In following these best practices, the Academy conducts a Job Analysis Study every five (5) years to ensure content validity of the CCRA Examination. Program content validity is demonstrated with a comprehensive job analysis conducted and analyzed by experts, with data gathered from practitioners within the profession. The process utilizes knowledge and task focused guidelines to assess clinical research professionals' competence, and determine the level of importance and frequency of specific knowledge and tasks required to perform in the role of a clinical research associate. View Executive Summary for the most recent Job Analysis Study.

Using the CCRA Detailed Content Outline (DCO)

The CCRA DCO was constructed from the results of the most recent (2015) Job Analysis Study. The results of the study provided the framework for the knowledge and tasks important to the role of a CCRA and therefore the content of the CCRA Exam. To be certified, a CRA is expected to have proficiency in the six (6) main content areas of clinical research, displayed in the chart below. The percent of questions dedicated to each content area are provided.

	Content Areas	Percentage of Items on Exam
I.	Scientific Concepts and Research Design	12%
II.	Ethical and Participant Safety Considerations	20%
III.	Product Development and Regulation	10%
IV.	Clinical Trial Operations (GCPs)	25%
V.	Study and Site Management	23%
VI.	Data Management and Informatics	10%
	Total	**100%**

Certified Clinical Research Associates (CCRAs) are expected to have general knowledge of:

- laboratory terminology, tests, and procedures
- basic math, including adding, subtracting, multiplying, dividing, and calculating percentages

The specific knowledge and tasks identified as important are provided in the CCRA DCO, below. Therefore, to prepare to take the CCRA Exam, one should study this outline and especially consider the underlying knowledge, skills, and abilities needed to perform as a CCRA. It is recommended that an eligible CCRA Exam candidate use this outline to identify knowledge gaps for constructing a relevant preparation plan.

Certified Clinical Research Associate (CCRA®) Examination Detailed Content Outline

(Effective 1 January 2017)

As defined by the most recent ACRP Job Analysis Survey, a CCRA® shall have proficient **knowledge** (middle column) in the following six (6) content areas of clinical research. A CCRA typically uses this knowledge to perform the **tasks** listed (last column).

Content Area	CCRAs must demonstrate proficient knowledge within the following areas:	CCRAs typically perform the following tasks:
I. Scientific Concepts and Research Design (12%)	**1.1 components of a product development plan (e.g., timelines)**	Review background information (e.g., product development plan, IB)
		Identify and/or explain study objective(s) and endpoints
		Identify the expected or unexpected results associated with investigational products
	1.2 elements of a protocol	Identify and/or explain study design
		Identify issues requiring protocol amendments
		Develop and/or Evaluate data collection tools (e.g., case report form (e/CRF), electronic data capture (EDC)) for consistency with protocol
	1.3 elements of an Investigational Brochure (IB) and/or investigational device use (instructions for use)	Identify the safety and expected therapeutic effects of the investigational product.
		Review background information (e.g., product development plan, IB)
		Identify the expected or unexpected results associated with investigational products
	1.4 elements of and rationale for subject eligibility requirements	Develop and/or follow a recruitment strategy
		Evaluate study for feasibility (site determining ability to successfully conduct the study)
		Re-evaluate the recruitment strategy as needed
	1.5 rationale for complying with a protocol	Develop or participate in protocol training
		Ensure compliance with study requirements and regulations
		Ensure investigator/site protocol compliance
	1.6 study design characteristics (e.g., double-blind, crossover, randomized)	Identify and/or explain study design
		Identify and/or explain study objective(s) and endpoints
		Develop and/or follow a study plan (e.g., management plan, monitoring plan, etc.)
	1.7 study objective(s) and end	Identify and/or explain study objective(s) and

Content Area	CCRAs must demonstrate proficient knowledge within the following areas:	CCRAs typically perform the following tasks:
	points/outcomes	endpoints
		Plan, conduct and/or participate in training of the investigational staff
		Develop and/or Evaluate data collection tools (e.g., case report form (e/CRF), electronic data capture (EDC)) for consistency with protocol
	1.8 use of supplemental/rescue/comparator product in study design	Identify and/or explain study design
		Minimize potential risks to subject safety
		Ensure proper storage, dispensing, handling, and disposition of investigational product and related supplies
	1.9 treatment assignments (e.g., randomization, open label, registries)	Identify and/or explain study design
		Ensure adequacy of investigational product and other supplies at site
		Monitor investigational product expiration and/or manage resupply
2. Ethical and Participant Safety Considerations (20%)	**2.1 adverse events classification, documentation and reporting**	Differentiate the types of adverse events that occur
		Maintain follow-up to determine resolution of adverse event(s)
		Verify appropriate reporting and documentation of adverse event(s)
	2.2 blinding procedures	Ensure proper storage, dispensing, handling, and disposition of investigational product and related supplies
		Identify and/or explain study design
		Identify and/or explain study objective(s) and endpoints
	2.3 components of subject eligibility requirements	Assess, manage, and/or review subject laboratory values, test results, and alerts
		Plan, conduct and/or participate in training of the investigational staff
		Inform the sponsor and IRB/IEC of any deviations from the protocol and document as appropriate
	2.4 confidentiality and privacy requirements	Ensure compliance with electronic data requirements (e.g., passwords and access)

Content Area	CCRAs must demonstrate proficient knowledge within the following areas:	CCRAs typically perform the following tasks:
		Ensure access to source data by authorized parties, and protect confidentiality by limiting unauthorized access
		Comply with subject privacy regulations
	2.5 elements of the IB	Identify the safety and expected therapeutic effects of the investigational product.
		Differentiate the types of adverse events that occur
		Review the Investigators' Brochure
	2.6 elements of the informed consent form	Ensure adequate consent and documentation
		Develop and/or review informed consent form
		Prepare and/or submit documents for IRB/IEC and/or sponsor review/approval
	2.7 informed consent process requirements	Verify adequate implementation and documentation of the informed consent process
		Identify and/or address potential ethical issues involved with study conduct
		Prepare the study site for audits and inspections
	2.8 protection of human subjects	Minimize potential risks to subject safety
		Assess, manage, and/or review subject laboratory values, test results, and alerts
		Assess subject safety during study participation
	2.9 protocol deviation/violation identification, documentation, and reporting processes	Inform the sponsor and IRB/IEC of any deviations from the protocol and document as appropriate
		Prepare for and/or participate in audits and inspections
		Identify issues and recommend investigator/site corrective actions
	2.10 recruitment plan/strategies	Re-evaluate the recruitment strategy as needed
		Develop and/or follow a recruitment strategy
		Verify investigator/site feasibility
	2.11 safety monitoring	Ensure timely review of safety data
		Reconcile safety and clinical databases
		Assess subject safety during study participation

Content Area	CCRAs must demonstrate proficient knowledge within the following areas:	CCRAs typically perform the following tasks:
	2.12 subject discontinuation criteria/procedures	Document reasons for subject discontinuation (i.e., causes, contact efforts)
		Assess subject compliance
		Minimize potential risks to subject safety
	2.13 subject retention strategies	Develop and/or implement study education plan and/or tools for subjects
		Develop project/trial management tools
		Select trial sites for participation
	2.14 subject safety issues	Maintain follow-up to determine resolution of adverse event(s)
		Oversee the management of safety risks (e.g., clinical holds, product recalls)
		Assess subject safety during study participation
	2.15 vulnerable subject populations	Identify and/or address potential ethical issues involved with study conduct
		Comply with IRB/IEC requirements
		Ensure adequate consent and documentation
	2.16 conflicts of interest in clinical research	Identify and/or address potential ethical issues involved with study conduct
		Identify and report potential fraud and misconduct
		Investigate potential fraud and misconduct
3. Product Development and Regulation (10%)	**3.1 audit and inspection processes (preparation, participation, documentation, and follow-up)**	Prepare the study site for audits and inspections
		Prepare for and/or participate in audits and inspections
		Respond to or facilitate response to audit/inspection findings
	3.2 clinical development process (e.g., preclinical, clinical trial phases, device class)	Ensure compliance with study requirements and regulations
		Coordinate protocol and/or protocol amendments through appropriate approval processes (e.g., IRB/IEC, sponsor, regulatory authority)
		Prepare and/or submit documents for IRB/IEC and/or sponsor review/approval
	3.3 elements of fraud and misconduct	Identify and/or address potential ethical issues involved with study conduct
		Identify and report potential fraud and

Content Area	CCRAs must demonstrate proficient knowledge within the following areas:	CCRAs typically perform the following tasks:
		misconduct
		Investigate potential fraud and misconduct
	3.4 IRB/IEC reporting requirements	Comply with IRB/IEC requirements
		Ensure IRB/IEC review/written approval of study and study documents
		Prepare and/or submit documents for IRB/IEC and/or sponsor review/approval
	3.5 IRB/IEC role, composition and purpose	Identify the role and proper composition of IRB/IECs
		Ensure IRB/IEC review/written approval of study and study documents
		Inform the sponsor and IRB/IEC of any deviations from the protocol and document as appropriate
	3.6 product development lifecycle	Review background information (e.g., product development plan, IB)
		Identify the safety and expected therapeutic effects of the investigational product.
		Manage study records retention and availability
	3.7 protocol and protocol amendment submission and approval processes	Coordinate protocol and/or protocol amendments through appropriate approval processes (e.g., IRB/IEC, sponsor, regulatory authority)
		Identify issues requiring protocol amendments
		Implement protocol amendments
	3.8 regulatory reporting requirements	Ensure compliance with study requirements and regulations
		Inform the sponsor and IRB/IEC of any deviations from the protocol and document as appropriate
		Verify appropriate reporting and documentation of adverse event(s)
	3.9 safety reporting requirements	Verify appropriate reporting and documentation of adverse event(s)
		Differentiate the types of adverse events that occur
		Oversee the management of safety risks (e.g., clinical holds, product recalls)
	3.10 significant milestones in the	Ensure timely review of study data

Content Area	CCRAs must demonstrate proficient knowledge within the following areas:	CCRAs typically perform the following tasks:
	evaluation of efficacy and safety (e.g., interim analysis result, DSMB review)	Develop and/or follow a study plan (e.g., management plan, monitoring plan, etc.)
		Ensure timely review of safety data
4. Clinical Trial Operations (GCPs); (25%)	**4.1 delegation of responsibilities**	Select qualified investigational staff
		Verify that investigational staff is qualified
		Develop or participate in protocol training
	4.2 elements of an effective corrective and preventive action (CAPA) plan	Create, document, and/or implement corrective and preventive action (CAPA) plans
		Document, communicate, and follow up on site visit findings
		Escalate significant findings as appropriate
	4.3 elements of and rationale for monitoring plan(s)	Develop and/or follow a study plan (e.g., management plan, monitoring plan, etc.)
		Develop and implement monitoring guidelines/plans
		Prepare, conduct, and/or participate in interim monitoring visit(s)
	4.4 elements of the investigator's brochure	Perform risk-based monitoring activities
		Assess, manage, and/or review subject laboratory values, test results, and alerts
		Review the Investigators' Brochure
	4.5 monitoring activities (source data review, source data verification)	Conduct co-monitoring/training visits
		Perform onsite monitoring activities
		Perform remote monitoring activities
	4.6 pre-study/site selection visit activities	Obtain/verify vendor credentials (e.g., lab certification/licensure)
		Schedule, coordinate, and/or participate in pre-study site visit
		Select trial sites for participation
	4.7 principal investigator responsibilities	Monitor accountability of investigational product
		Ensure appropriate staff, facility, and equipment availability throughout the study
		Identify and/or maintain Essential Documents required for study conduct
	4.8 principles of risk based monitoring	Perform risk-based monitoring activities
		Conduct source data review (SDR) and/or source data verification (SDV) remotely

Content Area	CCRAs must demonstrate proficient knowledge within the following areas:	CCRAs typically perform the following tasks:
		Ensure monitoring activities are conducted according to plan
	4.9 project feasibility considerations	Ensure consistency between the sites' standard operating procedures (SOPs) and the study requirements
		Evaluate study for feasibility (site determining ability to successfully conduct the study)
		Select trial sites for participation
	4.10 roles of various clinical trial entities (e.g., CROs, sponsors, regulatory authority, etc.)	Develop and/or follow a study plan (e.g., management plan, monitoring plan, etc.)
		Identify the role and proper composition of IRB/IECs
		Obtain/verify vendor credentials (e.g., lab certification/licensure)
	4.11 site close-out activities	Prepare, conduct, and/or participate in close-out monitoring visit(s)
		Transmit data to Data Management
		Reconcile investigational product and related supplies
	4.12 site initiation activities	Prepare, conduct and/or participate in study initiation activities
		Perform and/or verify equipment calibration and maintenance
		Verify Essential Documents required for study conduct
	4.13 site selection criteria	Ensure consistency between the sites' standard operating procedures (SOPs) and the study requirements
		Select qualified investigational staff
		Select trial sites for participation
	4.14 staff oversight	Review study related logs (e.g., site signature log, screening log)
		Verify that investigational staff is qualified
		Ensure consistency between the sites' standard operating procedures (SOPs) and the study requirements
	4.15 staff qualifications (site and	Verify that investigational staff is qualified

Content Area	CCRAs must demonstrate proficient knowledge within the following areas:	CCRAs typically perform the following tasks:
	monitor)	Develop or participate in protocol training
		Follow standards for handling hazardous goods (e.g., International Air Transport Association (IATA)
	4.16 staff training requirements	Develop or participate in protocol training
		Plan, conduct and/or participate in training of the investigational staff
		Ensure proper collection, processing, and shipment of specimens (e.g., centrifuge, preparation of slides, freezing, refrigeration)
	4.17 study close-out activities	Perform query resolution
		Verify Essential Documents required for study conduct
		Prepare, conduct, and/or participate in close-out monitoring visit(s)
5. Study and Site Management (23%)	**5.1 communication documentation requirements (e.g., telephone, email)**	Document, communicate, and follow up on site visit findings
		Perform remote monitoring activities
		Escalate significant findings as appropriate
	5.2 corrective and preventive action (CAPA) process(es) and plans	Create, document, and/or implement corrective and preventive action (CAPA) plans
		Escalate significant findings as appropriate
		Identify issues and recommend investigator/site corrective actions
	5.3 equipment and supplies use and maintenance	Manage study supplies (e.g., lab kits, case report forms)
		Ensure adequacy of investigational product and other supplies at site
		Perform and/or verify equipment calibration and maintenance
	5.4 investigational product accountability and documentation requirements	Monitor accountability of investigational product
		Manage investigational product recall
		Reconcile investigational product and related supplies

Content Area	CCRAs must demonstrate proficient knowledge within the following areas:	CCRAs typically perform the following tasks:
	5.5 investigational product characteristics (e.g., mechanism of action, stability, etc.)	Identify the expected or unexpected results associated with investigational products
		Ensure proper storage, dispensing, handling, and disposition of investigational product and related supplies
		Monitor investigational product expiration and/or manage resupply
	5.6 investigational product labeling requirements	Monitor investigational product expiration and/or manage resupply
		Reconcile investigational product and related supplies
		Identify and/or maintain Essential Documents required for study conduct
	5.7 investigational product packaging	Monitor investigational product expiration and/or manage resupply
		Reconcile investigational product and related supplies
		Ensure proper storage, dispensing, handling, and disposition of investigational product and related supplies
	5.8 investigational product reference materials (e.g., Investigational brochure, instructions for use, user manual)	Review the Investigators' Brochure
		Develop and/or implement study education plan and/or tools for subjects
		Identify the safety and expected therapeutic effects of the investigational product.
	5.9 investigational product shipment	Ensure proper storage, dispensing, handling, and disposition of investigational product and related supplies
		Manage investigational product recall
		Ensure adequacy of investigational product and other supplies at site
	5.10 investigational product storage	Ensure proper storage, dispensing, handling, and disposition of investigational product and related supplies
		Ensure appropriate staff, facility, and equipment availability throughout the study
		Review study related logs (e.g., site signature log, screening log)
	5.11 non-compliance management	Identify and report potential fraud and

Content Area	CCRAs must demonstrate proficient knowledge within the following areas:	CCRAs typically perform the following tasks:
		misconduct
		Ensure investigator/site protocol compliance
		Escalate significant findings as appropriate
	5.12 project timelines	Develop and/or follow a study plan (e.g., management plan, monitoring plan, etc.)
		Develop project/trial management tools
		Evaluate study for feasibility (site determining ability to successfully conduct the study)
	5.13 purpose of and process(es) for protocol compliance	Ensure investigator/site protocol compliance
		Perform onsite monitoring activities
		Ensure proper collection, processing, and shipment of specimens (e.g., centrifuge, preparation of slides, freezing, refrigeration)
	5.14 roles of various clinical trial entities (e.g., CROs, sponsors, regulatory authority, etc.)	Identify the role and proper composition of IRB/IECs
		Escalate significant findings as appropriate
		Respond to or facilitate response to audit/inspection findings
	5.15 sample collection, shipment, and storage requirements	Ensure proper collection, processing, and shipment of specimens (e.g., centrifuge, preparation of slides, freezing, refrigeration)
		Perform and/or verify equipment calibration and maintenance
		Review study related logs (e.g., site signature log, screening log)
	5.16 subject compliance assessment	Assess subject compliance
		Ensure investigator/site protocol compliance
		Develop and/or implement study education plan and/or tools for subjects
	5.17 subject responsibilities for study participation	Develop and/or Evaluate data collection tools (e.g., case report form (e/CRF), electronic data capture (EDC) for consistency with protocol
		Verify adequate implementation and documentation of the informed consent process
		Document reasons for subject discontinuation (i.e., causes, contact efforts)

Content Area	CCRAs must demonstrate proficient knowledge within the following areas:	CCRAs typically perform the following tasks:
	5.18 subject visit activities	Assess subject compliance
		Reconcile investigational product and related supplies
		Develop project/trial management tools
6. Data Management and Informatics (10%)	**6.1 data management activities**	Review completed eCRF/CRF
		Transmit data to Data Management
		Manage study records retention and availability
	6.2 data privacy principles	Ensure compliance with electronic data requirements (e.g., passwords and access)
		Ensure access to source data by authorized parties, and protect confidentiality by limiting unauthorized access
		Comply with subject privacy regulations
	6.3 elements and purposes of data collection tools (e.g., eCRF, EDC)	Develop trial management tools (e.g. subject study calendar, source documents, retention material)
		Develop source document templates
		Evaluate data collection tools (e.g., case report form (e/CRF), electronic data capture (EDC)) for consistency with protocol
	6.4 elements of and process for data query	Manage study records retention and availability
		Prepare study summary and/or close-out letter for IRB/IEC
		Prepare and/or participate in close-out monitoring visit(s)
	6.5 elements of pharmacovigilance (e.g., CIOMS, IDMC/DSMB, safety databases)	Perform query resolution
		Collect, record, and report accurate and verifiable data
		Review completed eCRF/CRF
	6.6 essential documents for the conduct of a clinical trial (e.g., trial master file)	Ensure timely review of safety data
		Collect, record, and report accurate and verifiable data
		Minimize potential risks to subject safety
	6.7 record retention and destruction practices and requirements	Identify and/or maintain Essential Documents required for study conduct
		Manage study records retention and availability

Content Area	CCRAs must demonstrate proficient knowledge within the following areas:	CCRAs typically perform the following tasks:
		Maintain study related logs (e.g., site signature log, screening log)
	6.8 source data review (SDR) and source data verification (SDV) purpose and process	Manage study records retention and availability
		Maintain study related logs (e.g., site signature log, screening log)
		Ensure consistency between the sites' standard operating procedures (SOPs) and the study requirements
	6.9 source documentation requirements	Collect, record, and report accurate and verifiable data
		Perform query resolution
		Ensure and document follow-up medical care for study subjects, as applicable
	6.10 study documentation practices (accurate, complete, timely, legible, dated, and identify the trial)	Develop source document templates
		Collect, record, and report accurate and verifiable data
		Evaluate data collection tools (e.g., case report form (e/CRF), electronic data capture (EDC)) for consistency with protocol