ACRP

CERTIFIED CLINICAL RESEARCH ASSOCIATE

CERTIFIED CLINICAL RESEARCH ASSOCIATE
CCRA

Certification Handbook

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

Table of Contents

APPLYING FOR CERTIFICATION 3
Welcome and Congratulations 3
ACRP Certification Overview 3
Application Deadline 3
Confidentiality 3
Application Process and Requirements 3
Professional Level Experience Requirements 3
CCRA Eligibility Requirements 3
CRA Essential Duties 4
Substitution for Work Experience Requirements 5
Application and Exam Fees 5
Application for Certification 6
Services for People with Disabilities 6
Completing the Application Form 6
Submitting the Application 6
Receipt of Application 7
THE ELIGIBILITY REVIEW PROCESS 7
Eligibility Reviewers 7
Confirmation of Eligibility 7
CRA EXAMINATION INFORMATION 8
Exam Structure 8
Exam Delivery 8
Language 8
Exam Administration 8
Examination Window 8
Exam Appointment Scheduling 8
Confirmation Number 9
Confirming Your Appointment 9
Rescheduling Your Appointment 9

Cancellations, No Shows, Re-Examination, Refunds and Transfers 9
Preparing for the Exam 10
What's Covered on the Exam? 10
Detailed Content Outline 10
Preparation Support 11
Further Study Tips 11
Taking the Exam 11
Exam Appointment Arrival 12
Required Identification 12
Exam Security and Test Center Guidelines 12
Resources Available at the Test Center 12
Exam Scores 13
Exam Results and Notification 13
CCRA, CCRC, CPI Exam Updates for 2017 13
Detailed Content Outline (2010) for the Clinical Research Associate Exam 14
Appendix 18

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, during a 24-day period in March and September, 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 a CCRA. 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 15 for the September examination. Applications received by June 15 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 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: The Academy 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.

CCRA Eligibility Requirements

In order to be deemed eligible to take the CRA Certification exam, applicants must be able to document (through a detailed CV or resume and job description) that they:

- Work independently of the investigative staff conducting the research at the site or institution. This means they do not report to the PI or site manager and that they do not have the ability to change or manipulate data, ***AND;***

- Work on behalf of the sponsor. This means that they are contracted by the "sponsor" to perform an independent monitoring function. The "sponsor" can be a pharmaceutical or device company, a government or granting agency, a university department, a physician, etc., ***AND;***
- Perform ***EACH*** of the CRA Essential Duties as detailed below for a ***required minimum number of hours***. Hours performing the CRA 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. See below:

CCRA Eligibility Requirements At least one of the options below should be met **before applying** for the CCRA program.			
	Education	**Minimum Hours Performing Essential Duties**	**Required Documentation of Performed Essential Duties**
Option 1	▪ Bachelor's Degree (or higher) ***OR*** ▪ Registered Nurse (RN)	3,000 hours*	Detailed CV/résumé ***and*** Job Description
Option 2	▪ Associate's Degree	4,500 hours*	Detailed CV/Résumé ***and*** Job Description
Option 3	▪ Other, such as LPN, LVN, Medical Assistant, Lab Technician ***OR*** ▪ High School Diploma	6,000 hours*	Detailed CV/Résumé ***and*** Job Description

*see section for options of substitutions for work experience

CRA Essential Duties

As defined by the Academy, and determined through ACRP's 2010 Job Analysis Survey, clinical research associates who are eligible for CRA certification must document cumulative performance of **each** of the following Essential Duties during the dates of employment listed on the application:

- Verify that the research site personnel, including the investigators, are conducting the study according to the clinical protocol, "Good Clinical Practices", and regulatory requirements;
- Ensure reporting of adverse events from research site staff to the sponsor and the IRB/IEC;
- Verify that the data in the Case Report Forms (CRFs/eCRFs) are in agreement with the source documents (source data verification);
- Review accuracy and completeness of site records (site study file, query resolution, and other data collection tools);
- Verify Investigational Product accountability;
- Complete reporting and ensure management and resolution of all these activities (e.g., visit reports, trial management tracking system);
- Conduct routine monitoring (onsite or remote) on behalf of the clinical trial sponsor.

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)

The Academy acknowledges that there is a shared knowledge base between CCRC and CPI certificant holders and those who seek the CCRA designation. Any candidate for the CCRA designation who has a current CCRC or CPI designation will have achieved a valid substitute for 1,500 hours of the required professional experience performing the essential duties of a CRA.

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 CCRA 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/search.**

The Academy provides a list of academic clinical research programs which have been evaluated to meet the current waiver requirements. Click to view the **Accepted Academic Clinical Research Programs List**. This list is not considered exhaustive and is not designed to represent all academic offerings.

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:

	Early Bird Rate* May 2 – June 15, 2016	**Regular Rate June 16 – August 15, 2016**
Application Fee *(non-refundable)*	$125	$200
Exam Fee *(refundable)*	$325	$325
TOTAL DUE:	**$450**	**$525**

*Early Bird pricing applies for anyone applying early and always applies for ACRP Members throughout the application period.

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

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 or via a printable method.

The following must be uploaded or 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

*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

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.**

Completing the Application Form

There are two ways candidates can complete their applications: online (recommended) or a printable version*.

Both versions are accessible on our website at **www.acrpnet.org/certification.** 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 printable version 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 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 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

Our Eligibility Reviewers are clinical research professionals hired by the Academy 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 three level 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.

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 the 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.

CRA EXAMINATION INFORMATION

Exam Structure

The CRA Exam is designed as a practice-based exam to assess proficiency of the five (5) core knowledge areas:

1. Investigational Product Management
2. Protocol
3. Safety
4. Trial Management
5. Trial Oversight

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 September 2016 testing window begins September 8 and concludes October 1. 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. For detailed assistance with selecting a test center online, view **www.acrpnet.org/PDF/ExamSites.pdf**.

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 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

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. However, due to updated eligibility requirements in 2017, a new application will have to be submitted and application review will be conducted. The application fee will be discounted for re-examination candidates only.

*Please see section on CCRA, CCRC, CPI Exam Updates for 2017 for information on new eligibility requirements.

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, the Academy will mail a refund check to the original payer.

Transfers
The one-time transfer option is not available this examination period. Candidates will not be able to transfer from September 2016 to March 2017, as eligibility requirements will have changed. This will require all applicants to go through additional review toward the new 2017 eligibility requirements*. Applicants must cancel their exam and will receive a refund of the exam fee, only.

*Please see section on CCRA, CCRC, CPI Exam Updates for 2017 for information on new eligibility requirements.

Preparing for the Exam

The CRA 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.

The best preparation is to understand the CRA 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, as further explained on page 15.

What's Covered on the Exam?

To be certified, CRAs, 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 2010 ACRP Job Analysis Survey, a careful description of the tasks performed by clinical research associates. 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 CRA.

Study Texts
The ACRP ICH Reference Guide puts all five resources in one place for your convenience and ease of use.

ACRP Certification exams are based on four ICH Guidelines: (1) Guideline for Good Clinical Practice E6(R1); (2) Definitions and Standards for Expedited Reporting E2A; (3) General Considerations for Clinical Trials E8; (4) Statistical Principles for Clinical Trials E9; and, the Declaration of Helsinki (DoH).

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: 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 **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.

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.

CCRA, CCRC, CPI Exam Updates for 2017

Starting in 2017, ACRP Certification exam content will be realigned. A recent Job Analysis Study, which included a survey of thousands clinical research professions, confirmed the knowledge and tasks required for performing competently within one's role. This study, conducted every five (5) years ensures exam content is continuously aligned with practice. The following improvements are the result of a recent Job Analysis Survey to collect descriptive information about the tasks performed by clinical researchers and the knowledge, skills, or abilities requisite to job competence in the field.

- Exam Content: The Detailed Content Outlines (DCOs) are aligned with the Core Competency Framework for clinical research professionals and contain knowledge areas that reflect your current practice as a monitor, coordinator, or investigator.
- Eligibility Requirements: Essential duties performed have been updated.
- Number of work experience hours/years required based on education.

- Holding one ACRP Certification can be used as a substitution toward some work experience for earning a second ACRP Certification.

For more information related to the 2017 updates, please click here or contact us at certification@acrpnet.org.

Detailed Content Outline (2010) for the Clinical Research Associate Exam

The Detailed Content Outline (DCO) is derived from the 2010 ACRP Job Analysis Survey. The September Exam period marks the final administration of the CRA exam using the 2010 content. *Note: Exams administered in 2017 will cover the content of the most recent Job Analysis conducted through 2015.*

Each question on the exam is based on the DCO. Therefore, to prepare to take the exam, one should study this outline and especially consider the underlying knowledge, skills, and abilities needed to perform as a clinical research associate. **To be certified, a CRA is expected to have *proficiency* in five (5) core knowledge areas found on the Detailed Content Outline (DCO).**

Note: The percentage of questions allocated to each of the five (5) core knowledge areas is noted within the DCO.

Certified Clinical Research Associates (CCRAs) shall have proficiency in:

I. Investigational Product Management (10%)

- Develop and update the instructions for use of investigational product
- Initiate shipment of investigational product to site
- Ensure adequacy of investigational product and other supplies at site
- Ensure randomization and emergency codes of investigational product have been maintained
- Ensure proper storage, dispensing, handling, and disposition of investigational product and other supplies
- Reconcile investigational product and other supplies
- Maintain accountability of investigational product
- Retrieve investigational product and calculate subject compliance
- Maintain randomization and emergency codes of investigational product dispensing

Using knowledge of:

- Investigational product (e.g., package insert, report of prior investigations, Investigator's Brochure)
- Investigational product inventory
- Investigational product accountability
- Investigational product storage
- Packaging and labelling
- Product development
- Supplemental/ rescue/ comparator product
- Investigational product compliance (e.g., protocol, standard operation procedures, local governance)
- Accountability records

II. Protocol (20%)

- Review product development plan
- Identify study objective/design
- Develop the protocol (e.g., inclusion/exclusion criteria, procedures, schedule of events, safety and efficacy parameters)
- Evaluate protocol for scientific soundness
- Evaluate protocol for feasibility
- Evaluate congruence of data collection tools (e.g., case report form (CRF), electronic data capture (EDC) with the study protocol

- Verify the eligibility of potential trial subjects
- Contribute to protocol development
- Coordinate protocol approval process
- Review protocol for feasibility
- Review protocol during investigator's meeting
- Execute study per protocol
- Recommend and Implement protocol amendments

Using knowledge of:

- Protocol development
- Protocol submission and approval procedures
- Clinical trial phase
- Study design characteristics (e.g., double-blind, crossover, randomized)
- Study objective
- Description of procedures
- Amendment submission and approval procedures
- Inclusion/exclusion criteria
- Statistical plan

III. Safety (25%)

- Assess safety during trial participation
- Minimize potential risks to subject safety
- Oversee safety risks (e.g., clinical holds, product recalls)
- Ensure adverse events reporting is documented (e.g., serious, severe, moderate, mild, expected, unexpected)
- Ensure reasons for subject discontinuation are documented (i.e., causes, contact efforts)
- Conduct study-related procedures and monitor the safety of the trial subjects and investigational staff
- Manage and motivate the investigational staff and other disciplines involved, and take measures to minimize any potential risks
- Review common laboratory values and alerts
- Identify expected or unexpected results associated with investigational products
- Maintain follow-up to determine resolution of adverse event
- Conduct safety monitoring/reporting activities

Using knowledge of:

- Investigator's Brochure
- Safety monitoring
- Safety and clinical databases
- Subject safety issues (e.g., toxicity, significant lab values)
- Vulnerable subject populations
- Adverse events reporting
- Serious adverse events reporting
- Safety reporting requirement

IV. Trial Management (30%)

- Verify investigator/site feasibility
- Develop timelines for conducting and completing the clinical trial
- Prepare and conduct initiation activities
- Ensure appropriate training of the investigational staff
- Develop a recruitment strategy and study management plan
- Follow a recruitment strategy and study management plan
- Review, clarify, and obtain data changes from sites
- Schedule and coordinate pre-study site visit

- Identify minimum regulatory document requirements for site trial master file (e.g., country-specific regulatory documents)
- Ensure IRB/IEC review/approval of study and study documents
- Facilitate site budget/contract approval process
- Develop Case Report Forms (e.g., CRFs, eCRFs)
- Develop CRF completion guidelines
- Develop monitoring guidelines/plans
- Develop project tools
- Submit documents to regulatory authorities
- Document and communicate site visit findings
- Ensure clinical trial registry requirements are met
- Ensure timely review of study data (e.g., laboratory results, x-rays)
- Maintain current vendor credentials (e.g., lab certification/licensure and normal ranges)
- Prepare and conduct interim monitoring visit(s)
- Prepare and conduct close-out monitoring visit(s)
- Reconcile payments to sites per contract
- Document protocol deviations/violations
- Reconcile safety and clinical databases
- Conduct co-monitoring/training visits
- Perform remote monitoring activities
- Train site personnel on Sponsor/CRO and regulatory requirements for study conduct (e.g., protocol procedures, EDC)
- Transmit CRFs to data management
- Review CRF queries from data management
- Coordinate study monitoring visits
- Draft study specific tools (e.g., source document, tracking tools)
- Implement corrective actions plans
- Maintain trial master file (e.g., regulatory binder)
- Manage study supplies (e.g., lab kits, case report forms)
- Comply with subject privacy regulations
- Manage study issues

Using knowledge of:

Site Activities

- Contract budget negotiations and approval process
- Project feasibility
- Project timelines
- Monitoring guidelines/plan and tools
- Study project tools
- Staff qualifications
- Staff roles and responsibilities
- data management activities
- Plan for staff oversight
- Investigator qualifications/ site selection (e.g., therapeutic area, education, experience)
- Disposition of unused study-related materials (e.g., CRF at end of study, destruction of lab kits)
- Equipment and supplies (e.g., x-ray, computer, lab kits) and storage
- Study management plan (e.g., timelines, data management)
- Communication documentation (e.g., telephone, email)
- Pre-study site visit
- Investigator's meeting
- Site initiation
- Monitoring visit
- Close-out visit
- Site monitoring visit log
- Site signature log

- Delegation listing
- Trial master file (e.g., site, sponsor)
- Data management plan
- Data query resolution
- Electronic data (e.g., electronic health records, electronic case report forms)
- Recruitment plans/strategies
- Subject compliance
- Subject visit logistics
- Protection of human subjects
- Subject selection, screening, and recruitment
- Subject retention
- Subject discontinuation
- Subject reimbursement
- Good Clinical Practice (GCP)
- Regulatory documents
- Record retention
- Subject privacy regulations
- Case Report Form (CRF/eCRF)
- Visit reports (e.g., initiation, close-out)
- Final report
- Progress reports
- Essential documentation, subject related and non-subject related (e.g., past medical records, lab reports, protocol, IRB approvals)
- Informed consent
- Procedure manuals
- Source documentation
- Protocol deviations
- Indemnification/insurance
- Clinical trial registry

V. Trial Oversight (15%)

- Ensure consistency between the sites' standard operation procedures (SOPs) and the study requirements
- Ensure investigator/site protocol compliance
- Facilitate investigator/site corrective actions
- Oversee vendors (e.g. Contract Research Organizations (CROs)
- Ensure compliance with electronic data requirements (e.g., electronic health records, eCRF)
- Ensure adequate site management
- Prepare the study site for audits and inspections
- Respond to or facilitate response to audit/inspection findings
- Ensure proper collection, processing, and shipment of specimens (e.g., centrifuge, preparation of slides, freezing, refrigeration)
- Ensure proper adverse event reporting by the investigator
- Escalate problems to appropriate in-house management
- Investigate potential fraud and misconduct
- Report potential fraud and misconduct
- Ensure follow-up medical care for study subjects is documented, as applicable
- Ensure adequate consent and documentation
- Ensure staff, facility, and equipment availability throughout the study
- Ensure compliance with study requirements and regulations
- Prepare for audits, inspections, and follow up
- Ensure access to source data by authorized parties, in accordance with ICH-GCP, and protect confidentiality by limiting unauthorized access
- Ensure that IRB/IEC documentation is adequate and that details of the IRB/IEC composition are on file

Using knowledge of:

- Issues management (e.g., escalation)
- Audit preparation
- Regulatory standards
- Audit documents
- Project monitoring guidelines
- Project investigator supervision requirements

Appendix

The Certification Program Policies Manual