



CRA

CERTIFICATION GUIDE



Academy of Clinical Research Professionals
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Alexandria, VA 22314
www.acrpn.org

CERTIFICATION CHECKLIST

Before you begin the *Certification* application process, be sure to:

1. Read the entire CRA Certification Guide.

The CRA *Certification* Guide contains all the information you need to know about the exam, so please be sure to read it in full. You are required to attest to having read this information when submitting an exam application.

2. Verify Your Membership Status

In order to take advantage of the reduced member rate you must be an active member before beginning the application process. Log in to acrpnet.org to verify your member status. If you want to join before applying for your exam, join online at acrpnet.org. Once you join, logout of acrpnet.org, log back in, and begin the application process. If you do not wish to become an ACRP member, and do not wish to take advantage of the discounted member rate, proceed with the application process.

3. Have All Application Documentation Ready

All applications require you to submit supporting documentation in order for your application to be considered. Documentation required for CCRA applicants includes:

- CV or resume
- Job Description

Note: File sizes must be under 5 megabytes for online applications.

4. Submit Your Application Once

Please submit your application either online or via a printable application form (not both, to avoid duplicate charges). All required elements (application, supporting documentation, and full payment) must be submitted together at the same time.

5. After You Submit Your Application

You will receive an automatic email confirmation for applications submitted online. Please allow up to 10 business days for mailed or faxed applications. All applications undergo a thorough review process. Please allow up to 3 weeks for your eligibility email notification. To ensure you receive your notification, we recommend you add acrpnet.org to your safe senders list (contact your IT department for instructions).

Table of Contents

Topic	Page
Quick References	5
General Information	7
<i>What is Certification?</i>	7
Top Ten Reasons to Become Certified	7
About the Academy of Clinical Research Professionals	8
Eligibility and Application for the CRASM Program	9
<i>Certification</i> Eligibility Requirements	9
Clinical Research Education Programs	10
Essential Duties	10
Application Instructions	11
Fees	12
Eligibility Review	13
Ineligibility Decision Appeals Process	13
Confirmation of Eligibility and Testing Information	14
Withdrawal of Application	14
About the CRASM Exam	15
Written Exam	15
Language	15
Detailed Content Outline (DCO)	15
Exam Scores	20
Preparing for the CRASM Exam	21
Study Text	21
Further Study Tips	22
Steps to Preparing for the CRA SM Exam	23
Exam Scheduling and Testing Procedures	24
Rescheduling Exam	24
Emergencies (Rescheduling / Cancellations)	24
Transfer to Next Window	25
Reactivation	25
Cancellations	26
Emergencies (Documenting)	26
Refunds	27
Test Center Selection	27

Table of Contents (continued)

Topic	Page
Services for People with Disabilities	27
Exam Scheduling and Admission Details	28
Exam Security	29
Test Taking Strategies	29
Exam Results	30
Duplicate Certificates	30
Maintenance of <i>Certification</i>	30
Revocation of <i>Certification</i>	32
How are <i>Certification</i> Exams Developed?	32
Reliability Measurements	34
Frequently Asked Questions	34
Non-Discrimination Policy	37
Confidentiality	37
Verification of Credentials	37
<i>Certification</i> Mark Use	37
Discipline and Complaints Policy	37
Appendix 1 – Sample CV	38
Appendix 2 – Special Accommodations Request Form	39
Appendix 3 – Exam Transfer Request Form	40
Appendix 4 – Emergency Cancellation Form	41
Appendix 5 – Duplicate Certificate Request Form	42

QUICK REFERENCE QUESTIONS

Question type determines who needs to be contacted. Please refer to chart for common examples:

Question	Contact the Academy or Prometric?	Contact Information
Exam Registration Questions		
Exam Application Received?	ACRP Member Services	office@acrpnet.org
Didn't Receive Notification of Eligibility	The Academy	Certification@acrpnet.org
What is my Prometric Testing ID Number?	The Academy	Certification@acrpnet.org
How Can I Locate a Test Site?	Prometric website	www.prometric.com/ACRP
How Much Are Exam Fees?	ACRP website – Fees calculator	www.acrpnet.org
Exam Rescheduling (within SAME testing window)		
Exam Rescheduling greater than 29 days prior to exam	Prometric	800-853-6769
Exam Rescheduling 16- 29 days prior to exam	Prometric - \$25 fee	800-853-6769
Exam Rescheduling 5-15 days prior to exam	Prometric - \$50 fee	800-853-6769
No rescheduling permitted less than 5 days prior to exam date	The Academy	Certification@acrpnet.org
Exam Transfers/Cancellations		
Exam Transfers/Cancellation <i>greater than 29 days prior to exam</i>	<i>Both: Prometric FIRST to cancel appointment, then notify the Academy via email (Use Exam Transfer Request Form if transferring)</i>	Prometric: 800-853-6769 Email the Academy: Certification@acrpnet.org
Exam Transfers/Cancellation <i>16-29 days prior to scheduled exam</i>	<i>Both: Prometric FIRST to pay \$25, then notify the Academy via email (Use Exam Transfer Request Form if transferring)</i>	Prometric: 800-853-6769 Email the Academy: Certification@acrpnet.org

Exam Transfers/Cancellation <i>5-15 days prior to scheduled exam (no cancellations permitted less than 5 days prior)</i>	<i>Both:</i> Prometric FIRST to pay \$50, then notify the Academy via email – no refunds permitted < 5 days prior to scheduled exam (Use Exam Transfer Request Form if transferring)	Prometric: 800-853-6769 Email the Academy: Certification@acrpnnet.org
Post Exam Questions		
Change of Contact Information	ACRP Member Services	office@acrpnnet.org
General Contact Information		
Prometric Member Services	Prometric	800-481-6525
To report issues with your Prometric experience	Prometric	800-853-6769
Academy of Clinical Research Professionals (the Academy)	<i>Certification</i> Department	500 Montgomery Str, Suite 800 Alexandria VA 22314-1560 Phone: 703-254-8100 Fax: 703-254-8101 Email: Certification@acrpnnet.org

Welcome to the Certified Clinical Research Associate (CCRA®) Program

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 recognised and appreciated for what you do. And like most professionals, you want to become better at it. You look for opportunities for on-going meaningful professional development, and practical ways to evaluate your own work that will help you develop as a professional. This is one reason the Academy's CCRA® credential was created.

What is *Certification*?

Certification is a voluntary process to recognize individuals for meeting professional standards set by an impartial third-party. The Academy *Certification* is the formal recognition of clinical research professionals who have met eligibility requirements and demonstrated proficiency of specific knowledge and job-related skills by passing a standardized exam.

Academy *Certification* programs are the only ones in clinical research accredited by the National Commission for Certifying Agencies (NCCA). NCCA sets independent standards for the development and operation of certification programs. This assures the validity and credibility of the process; that the process reflects current, job-specific practice and fairness to candidates. For more information on the NCCA, please visit www.credentialingexcellence.org/ncca.

Top 10 Reasons to Be CCRA® Certified

1. **Credibility.** Academy *Certification* serves as an impartial, third-party endorsement of your knowledge and experience against international standards in clinical research. It adds to your credibility as a clinical researcher and sets you apart from other professionals.
2. **Improves career opportunities and advancement.** Academy *Certification* can give you an advantage when being considered for a promotion or other career opportunities. *Certification* through the Academy clearly identifies you as an employee who has demonstrated proficiency of internationally accepted clinical research principles, techniques, and application of best practices on-the-job.
3. **Increases on-the-job responsibilities.** Academy *Certification* is a clear indicator of your willingness to invest in your own professional development. Certified professionals are aware of the constantly changing environment around their profession and possess the desire to anticipate and respond to change.
4. **Enhances skills and knowledge.** Achieving *Certification* through the Academy requires training, studying, and keeping up-to-date with changes in the profession. *Certification* showcases your individual mastery by confirming proficiency in the field. Academy *Certification* also requires *Maintenance of Certification* every two years, to ensure you stay informed and continue to develop as a clinical research professional.
5. **Earnings potential.** Many clinical research professionals who have become Academy certificants experience salary and wage increases and/or bonuses based on their *Certification* status. In addition, Academy certificants are in high demand and aggressively recruited.
6. **Demonstrates your engagement.** Earning *Certification* through the Academy shows your peers, supervisors and, in turn, trial subjects, your commitment to your chosen career and the clinical research profession at-large, as well as your ability to perform to set standards.

7. **Strengthens the profession's image.** The Academy's *Certification Program* seeks to grow, promote, and develop certified professionals, who can serve as role models for Good Clinical Practice (GCP) in the clinical research field.
8. **Accomplishment.** The Academy's *Certification* is a reflection of personal achievement because you have validated your skill set, specific to the job role you perform, by meeting internationally recognized standards set forth via International Conference on Harmonization (ICH) Guidelines.
9. **Builds self-esteem.** *Certification* through the Academy is a step toward defining yourself beyond a job description or academic degree while gaining a sense of personal satisfaction.
10. **Recognition.** As an Academy certificant, you can expect increased acknowledgement from your peers for taking that extra step in your professional career.

About the Academy of Clinical Research Professionals

Founded in 2006, the Academy of Clinical Research Professionals (the Academy) is the certifying body responsible for the governance and administration of the only job role-specific, accredited credentials available to clinical research professionals. The Academy is an affiliate of the Association of Clinical Research Professionals (ACRP).

The Academy's Board of Trustees, elected by current certificants in good standing, is responsible for awarding the CCRA® credential, establishing eligibility criteria, examination content, passing scores, and maintenance requirements.

The Certified Clinical Research Associate (CCRA®) credential was first awarded in 1995. The program is open to any eligible clinical research professional regardless of membership affiliation. The program consists of an assessment of an eligible candidate's professional experience and each candidate's mastery of job-specific clinical research principles and techniques as measured by a written examination.

The Academy of Clinical Research Professionals adheres to the highest standards by bench-marking its practices against standards set for certification programs. The National Commission for Certifying Agencies (NCCA) of the National Organization for Competency Assurance (NOCA) has established criteria for certification agencies. In 2010, the Academy's CCRC® and CCRA® programs received NCCA accreditation.

What is Required for Certification?

In order to achieve certification, all applicants must meet the **Eligibility Requirements** and pass the **Written Exam** and then **Maintain** their designation every two (2) years. Those candidates who meet the eligibility requirements and pass the exam will be certified as having met the Academy standards for becoming a **CCRA®**, as adopted by the Academy.

Eligibility Requirements

A CRA is a professional who, regardless of job title, supervises, monitors, and supports the administration and progress of a clinical trial on behalf of a sponsor. The sponsor, whose intent is the research of pharmaceuticals, biologics, or devices, may employ these individuals either directly or indirectly via Contract Research Organizations (CROs) or as independent consultants or contractors. The CRA must be independent of the investigative staff conducting the research at the site or institution.

CCRA® Eligibility Requirements			
	Education	Work Experience Performing the Essential Duties	Required Documentation of Performance of Essential Duties
Option 1	<ul style="list-style-type: none"> Bachelors degree OR Masters degree OR Registered Nurse (RN) 	3,000 hours	Detailed CV /Resume AND Job Description submitted WITH application
Option 2	<ul style="list-style-type: none"> Bachelors degree OR Masters degree OR Registered Nurse (RN) AND <ul style="list-style-type: none"> Completion of a clinical research education program* of at least 216 hours AND accredited 	1,500 hours	Detailed CV/Resume AND Job Description AND Certificate of Completion from school submitted WITH application
Option 3	<ul style="list-style-type: none"> Associates degree 	4,500 hours	Detailed CV /Resume AND Job Description submitted WITH application
Option 4	<ul style="list-style-type: none"> Associated degree AND <ul style="list-style-type: none"> Completion of a clinical research education program* of at least 216 hours AND accredited 	3,000 hours	Detailed CV/Resume AND Job Description AND Certificate of Completion from school submitted WITH application
Option 3	<ul style="list-style-type: none"> Other, such as LPN, LVN, Medical Assistant, Lab Technician OR High School diploma 	6,000 hours	Detailed CV/Resume AND Job Description submitted WITH application
Option 4	<ul style="list-style-type: none"> Other, such as LPN, LVN, Medical Assistant, Lab Technician OR High School diploma AND <ul style="list-style-type: none"> Completion of a clinical research education program* of at least 216 hours AND accredited 	4,500 hours	Detailed CV/Resume AND Job Description AND Certificate of Completion from school submitted WITH application

*Clinical Research Education Programs

The Academy permits applicants who have completed a clinical research education program that meets the following standards to be used as a substitute for 1,500 hours of professional experience.

Acceptable programs must be:

- At least 216 contact hours in length ***AND***
- Include topical content that substantially maps to the CCRA® Essential Duties and/or the CCRA® Detailed Content Outline ***AND***
- Accredited by an accrediting agency recognized by the Council on Higher Education Accreditation (CHEA) or the U.S. Department of Education

A list of recognized accrediting agencies on the following websites:

- Council on Higher Education Accreditation (CHEA):
<http://www.chea.org/search/default.asp>
- Government (USDE):
<http://www.ed.gov/students/prep/college/diplomamills/index.html?src=rt>

If an applicant submits the application using an educational program as a substitute for 1,500 hours of CRA work experience, then the following information must be included on the applicant's CV (See Appendix 1 for Sample CV) ***and*** a certificate of completion must also be submitted:

- Name of School
- City, Country in which the school is located
- Program Title
- Name of Organization that accredits the institution providing the program
- Dates Attended (From-To)

Essential Duties:

As defined by the Academy, and determined through ACRP's 2010 Job Analysis Survey, Clinical Research Associate's who are eligible for CRA *Certification* must document 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) 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 visits on behalf of the clinical trial sponsor.

Applicants must submit a detailed resume or CV (see Appendix 1 for sample CV) and a job description with the exam application. This must include a description of the candidate's CRA job functions and specific employment dates. Do not include a list of study participation on your CV.

Application Instructions

Applicants must complete an application form in order to be considered for eligibility to take the Written Exam. We encourage all candidates to use the online application that can be found on the ACRP website at <http://www.acrpnet.org/CRACertification>. Applicants who must pay by check will need to complete a printable application and submit a hard-copy with their payment. If completing the printable application, make sure the application is received by the Academy by the deadline to avoid the late fee.

The exam dates and application **receipt** deadlines (NOT postmark deadlines) are as follows:

Exam Dates	Application Deadlines for Receipt of Application	Application Deadlines for Receipt of Application with Late Fee
March 1-10, 2012	January 23, 2012	January 24-February 6, 2012
September 6-15, 2012	July 31, 2012	August 1-14, 2012

To apply for an exam, an applicant must submit either the online or printable exam application along with a copy of a detailed resume or CV that shows job functions and specific employment dates, a job description, and the appropriate fees by the application receipt deadline.

Online and printable applications can be found at <http://www.acrpnet.org/CRACertification>

Application Method	Payment Method	Documents Required to be Submitted WITH Application	By Deadline Date
On-line via ACRP website	Credit Card	<ol style="list-style-type: none"> CV/Resume Job Description Educational Program Certificate (if required) <ul style="list-style-type: none"> Documents should be <i>uploaded</i> as part of application or <i>faxed</i> 	On-line Submission Complete and All Documents UPLOADED
Printable Form from ACRP website <u>Mailed</u> as Hard Copy	Check or Wire Transfer	<ol style="list-style-type: none"> CV/Resume Job Description Educational Program Certificate (if required) <ul style="list-style-type: none"> Documents should be <i>included</i> with mailed application 	Mailed Application and All Documents RECEIVED by ACRP
Printable Form from ACRP website <u>Faxed</u> as Hard Copy	Credit Card	<ol style="list-style-type: none"> CV/Resume Job Description Educational Program Certificate (if required) <ul style="list-style-type: none"> Documents should be <i>included</i> with mailed application 	Mailed Application and All Documents RECEIVED by ACRP

VERY IMPORTANT: Incomplete applications, or applications submitted without the correct fee, **will not be processed**. Submission of your application constitutes agreement that you have read, understood, and have agreed to abide by the ACRP/APCR Unified Code of Ethics.

An email confirmation is automatically sent once payment is processed. Applicants will also be sent an email that confirms that the application was received by the Academy. PLEASE NOTE: These

confirmations do not confer eligibility. A separate notification will be sent regarding an eligibility decision. Please take any necessary steps to prevent filtering of ACRP emails.

For those submitting the printable application, for the applicant's protection, it is highly recommended that the application be mailed to the Academy via certified mail, express parcel service, or a traceable courier to ensure receipt by the application receipt deadline. Faxed applications will be accepted if you are paying by credit card. Keep your fax confirmation for your records.

Fees

Only applications received with full payment and all required supporting documentation will be processed.

To activate the ACRP member rate, the applicant must join/re-join ACRP **before** applying for the exam.

To compare costs, feel free to use the cost calculator on the ACRP website at: view membership rates, visit the membership section of the website at: <http://www.acrpnet.org/popups/CRA-fee-calculator.html>

Applications submitted after the regular deadline, during the Extended Deadline period, incur an additional late fee.

	CCRA® Application and Exam Fees			
	Standard Fee <i>Regular Deadline</i>	ACRP-Member Fee <i>Regular Deadline</i>	Standard Fee <i>Extended Deadline</i>	ACRP-Member Fee <i>Extended Deadline</i>
Application Fee <i>Non refundable</i>	\$115	\$115	\$115	\$115
Exam Fee	\$583	\$383	\$583	\$383
Late Fee <i>Non refundable</i>	--	---	\$150	\$150
TOTAL AMOUNT DUE at Application	\$698	\$498	\$848	\$648

All exam fees include a non-refundable \$115 application fee regardless of eligibility status or cancellation. The late fee is also non-refundable.

All fees must be paid in full by check or credit card (American Express, VISA, or MasterCard). Corporate checks must reference each applicant's name.

Applicants are required to sign a disclosure statement attesting to the accuracy of the information provided as part of the application process. By submitting an application, applicants consent to and authorize the Academy to verify the candidate's academic and employment records.

It is the candidate's responsibility to submit all relevant documents at the time of application.

Employers must be listed on the candidate's application form. The Academy has the right to verify qualifications. By submitting an application, applicants consent to and authorize the Academy to verify the applicant's academic and employment records.

The Academy does reserve the right to request backup documentation to substantiate the reported information at any time.

The Eligibility Review process includes determining completeness of the application and determining whether or not the applicant meets the eligibility criteria for the exam. This process begins with one week of confirmation of receipt of the application. It can take up to one (1) month to review an application.

It is not unusual for an applicant to receive a request for additional and/or clarifying information from an Eligibility Reviewer. These requests will come via email. Applicants will have seven (7) calendar days to respond to the request. Applicants who do not respond to the request for additional or clarifying information will automatically have their applications determined ineligible. **INCOMPLETE** and therefore ineligible applications will be refunded the exam fee ONLY and candidates will need to re-apply to the program and pay all fees. Incomplete applications will not be returned.

If an applicant is determined to be **ELIGIBLE**, the candidate will be notified via email two to three weeks after receipt of the complete application, with further instructions as to how to schedule his/her exam appointment.

If an applicant is determined to be **INELIGIBLE** during initial review, the application is **automatically** reviewed by a second reviewer. If the second reviewer ALSO determines the applicant to be ineligible, the application is **automatically** sent to the Director of Certification for a third review. Applicants are notified via email at each step of the review with an explanation of the deficiency identified.

If, after the three levels of review, the applicant is still determined to be Ineligible, the applicant can choose to appeal to the Academy Board of Trustees. However, after the third level of review by the Director of Certification, applicants can no longer submit NEW documents to overturn an eligibility decision.

Applicants found to be INELIGIBLE and who do not initiate the Appeals Process will automatically be refunded the Exam Fee ONLY within a month.

Ineligibility Decision Appeals Process

The Academy makes every attempt to make fair and accurate eligibility decisions based on the information provided by the applicants. Should a decision of ineligibility be made, the applicant will be notified by email with an explanation of the deficiency identified. Candidates who do not meet the eligibility requirements may appeal the decision of the denial to the Academy under specific conditions. The applicant shall submit a written notice of appeal no more than 7 (seven) days following receipt of notice of denial by the Director of Certification.

In the written notice of appeal, the applicant shall submit additional, written, factual documentation to support his/her appeal with an explanation of why he or she believes the reviewer erred in his/her decision. No new documents pertaining to the applicant's eligibility shall be accepted during the appeals

process. The applicant shall bear the burden of proving the denial of eligibility was based on erroneous factual determination of the reviewer.

The Academy Board of Trustees will review the candidate's application and accompanying documents and the appeal letter. The applicant will be notified via hard-copy mail of the decision of the Academy Board of Trustees and the decision shall be final.

Confirmation of Eligibility and Testing Information

Candidates who are determined to be eligible will receive a confirmation notice via email. The notice will include an Eligibility ID and instructions as to how to schedule a personal exam appointment.

A candidate will use his/her Eligibility ID number to log onto the Prometric website to schedule his/her personal exam appointment. Candidates will be able to select the site, exam date, and time.

For further details on the procedures for scheduling exam appointment and the test taking experience, please see page 24.

Withdrawal of Application

Once a candidate submits an application for certification, it cannot be withdrawn. Candidates who wish to discontinue the certification process may submit a request via email to certification@acrpnet.org to obtain a refund of the Exam Fee only. If a candidate submits such a request, AND the candidate has received an Eligibility ID, the ID number will be invalidated.

Written Exam

The Certified Clinical Research Associate (CCRA®) Examination is designed as a practice-based exam for individuals involved in the performance of the essential duties of a clinical research Associate to assess proficiency of the five (5) core knowledge areas:

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

The examination consists of 125 multiple-choice questions. (25 of these questions are pre-test items and do not affect a candidate's score.) 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. Questions test recall, application, and analysis. Some questions use hypothetical scenarios. The exam content is based on a process of expert peer review, performed by the Global CCRA® Exam Committee. There are no "trick" questions on the examination. There is no penalty for guessing.

Each candidate is allowed a maximum of three (3) hours to complete the exam.

Language

The CRA *Certification* Exam is provided in English.

Exam candidates may bring a hard-copy English-German / Spanish / Chinese / Hindi / etc., translation dictionary to the exam. Electronic dictionaries are not permitted. The dictionary will be inspected by the proctor prior to and after the exam is completed. Any attempt to compromise the exam will be grounds for immediate dismissal from the site, invalidation of the exam score, and possible legal action. Use of dictionaries is discouraged as this uses valuable testing time.

What is Covered On the Exam?

Certified Clinical Research Associates (CCRA®s) are expected to have general knowledge of:

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

As defined by the 2010 ACRP Job Analysis Survey, a Certified Clinical Research Associate (CCRA®) shall have proficiency in the following areas of clinical research:

Detailed Content Outline (DCO)

I. Investigational Product Management

- 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 labeling
- Product Development
- Supplemental/ rescue/ comparator product
- Investigational product compliance (e.g., protocol, standard operation procedures, local governance)
- Accountability records

II. Protocol

- 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

- 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 requirements

IV. Trial Management

- 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
- Regulatory documents
- Record retention
- Subject privacy regulations
- Case Report Form
- 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

- 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

Exam Scores

Prometric, the Academy's professional testing partner, scores all exams. One point is granted for each correct answer. There is no penalty assessed for an incorrect answer; points are scored only for correct answers. The number of questions answered correctly is a candidate's "raw score."

The "Total Scaled Score" will determine whether a candidate has passed the exam. This scaled score is statistically derived from the candidate's raw score and can range from 200 – 800. The passing **scaled** score for the CCRA® exam 600. The passing score reflects the minimum amount of knowledge a committee of experts has determined to be appropriate for *Certification*, according to accepted test development guidelines.

A criterion-referenced, standard-setting procedure and expert judgment are used to identify the passing point. The Academy uses the widely accepted Modified Angoff method. A candidate's ability to pass the exam depends on the amount of knowledge he or she demonstrates, not on the performance of other individuals taking the exam.

The reason for calculating **scaled** scores is that different forms or versions of the exam may vary in difficulty. As new versions of the exams are introduced, a certain number of questions in each content area are replaced by new questions. These changes may cause one version of the exam to be slightly easier or harder than another version.

To adjust for these differences in difficulty, a statistical procedure called "equating" is used. The goal of equating is to ensure fairness to all candidates. In the equating process, the minimum raw score (number of correctly answered questions) required to equal the passing scaled score is statistically adjusted (or "equated"). For instance, if the exam is determined to be more difficult than the base form of the exam, then the minimum raw score required to pass will be slightly lower than the passing scaled score. If the exam is a bit easier, then the passing raw score will be slightly higher than the passing scaled score. Equating helps ensure that the passing scaled score represents the same level of knowledge, regardless of which version of the exam a candidate takes.

A candidate scoring below the minimum scaled score has not been successful on the exam and cannot be certified. The exam is not scored on a curve. There are not a predetermined number of candidates permitted to pass. Your score does not depend on the other candidates who are testing with you that day.

Note: *The passing point set for the exam cannot be appealed. To score one point below the passing point is to be unsuccessful on the exam; to score at the passing point or higher is to pass the exam. A score higher than the passing point is not an indication of a higher proficiency in the subject matter.*

Specific questions on the exam, 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.

Preparing for the CCRA® Exam

The CCRA® Examination is intended to assess your proficiency of the body of knowledge required to perform in your job role as a Clinical Research Associate. The knowledge and tasks that are being tested are based on current practice in clinical research. It is testing your knowledge of ICH and GCP in the conduct of your job duties and responsibilities. It is not testing how your employer or you personally carry out those duties.

The CCRA® Examination is specific to the role that Clinical Research Associates play in the conduct of a clinical trial. 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 requires a general working knowledge of the roles and responsibilities of CRAs even if your employer does not require you to function in that role.

No two candidates come to the exam with the same knowledge base. Since experience and educational backgrounds are unique, these differences must be taken into consideration when determining a study method. While some individuals may take the exam without any preparation, the majority become involved in some form of exam preparation. Because the exams measure proficiency of the application of the knowledge required to be an effective CRA, it is impossible to train or teach to the exam. The best preparation is to understand the CRA knowledge requirements (see the *Detailed Content Outline* which was provided above) and their application to clinical research.

A Clinical Research Associate who has met the eligibility requirements to sit for the examination should have the knowledge needed to take and pass the examination. 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* which was provided above.

Study Texts

In order to prepare for the exam, all candidates should review and be familiar with the relevant regulations from:

- ICH Guidelines (E2A, E6, E8 and E9)
- Declaration of Helsinki* (latest version)

The most current copy of the ICH Guidelines and other regulatory materials may be found on the following websites:

- Declaration of Helsinki: <http://www.wma.net/en/20activities/10ethics/10helsinki/index.html>
- ICH Guidelines: <http://www.ich.org>

*Note of clarification on paragraph 29 of the WMA Declaration of Helsinki. The WMA is concerned that paragraph 29 of the revised Declaration of Helsinki (October 2000) has led to diverse interpretations and possible confusion. It hereby reaffirms its position that extreme care must be taken in making use of a placebo-controlled trial and that in general this methodology should only be used in the absence of existing proven therapy. However, a placebo-controlled trial may be ethically acceptable, even if proven therapy is available, under the following circumstances:

- Where for compelling and scientifically sound methodological reasons its use is necessary to determine the efficacy or safety of a prophylactic, diagnostic, or therapeutic method; or
- Where a prophylactic, diagnostic, or therapeutic method is being investigated for a minor condition and the patients who receive placebo will not be subject to any additional risk of serious or irreversible harm.

All other provisions of the Declaration of Helsinki must be adhered to, especially the need for appropriate ethical and scientific review.

Further Study Tips

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

Some candidates find it helpful to form study groups, asking questions of each other and covering a wide variety of topics. The Academy does not, however, coordinate such groups. You might wish to contact your local ACRP chapter to see if they conduct study groups, or if you can help form one.

If you have time, take a workshop or attend a conference session on topics that you aren't as familiar with. **Any** professional development courses that cover clinical research topics will add to your knowledge base and therefore will help prepare for the exam. **However, 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 CCRA® Exam.**

Courses titled this way are at the discretion of the organization offering the course. Those creating the course have NOT had any inside information about the exam. The same information that is included in this Guide to help you prepare is publically available to those creating educational content. 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.

Steps To Preparing for the CCRA® Exam:

STEP 1: Assess your own professional experience: Read *carefully* through the *Detailed Content Outline* description provided in this guide. Compare the detailed description of knowledge and tasks, plus the proportion of questions, to your own professional experience. Rate your relative skill level and experience on a relatively simple scale of 0-5 (0 = no experience) as an indicator as to how prepared you are, and where to invest more of your study focus in preparing for the exam.

STEP 2: Start early and plan ahead: You must complete and submit your detailed application at least 45 days before the exam. *Don't* leave this until the last minute! Focus some learning time reading in every content category but spend extra time reading in those categories where your experience is limited. Match your study efforts in relation to the time you have available and the specific study needs you have identified for yourself. Every exam candidate will answer the same number of questions in every category.

STEP 3: Schedule Your Study Time. If you decide to set up a study group, you should hold weekly meetings that will take about two hours on one day/evening every week. Schedule flexible blocks of time into your day timer. The key is not to memorize what you read but to understand concepts behind ICH/GCP and best practices in each knowledge category area to supplement your experience in answering questions on the exam. Read at night, read on the subway, read over lunch, but read, Read, READ!

STEP 4: Assemble your study notes in a binder. It may help you to organize your study notes, articles, book summaries, etc. in a binder using either the eight topics of the study manual modules, or the six exam categories, or your own index. Let your experience guide you in your strongest areas and focus more time in your weaker areas in relation to the relative value that each area will be to you on the exam. Or, you can create flashcards to help review.

STEP 5: Choose the materials that are right for YOUR study plan. Choose a mentor or colleague who has more experience in the areas in which you are less familiar and ask them to review concepts with you. As you perform your daily responsibilities, think about the underlying principles that dictate you take a particular course of action.

STEP 6: Stick to your study group's plan: Pick a regular night and show up on time. Each of you has the same goal and everyone has something to offer. Sharing reading and exchanging book notes is a great way to lighten the load. Study groups foster friendships and provide an incentive to stay focused on your collective goal. Complete, don't compete.

STEP 7: Don't Panic! Follow the excellent pre-exam advice that the Academy provides and come to the exam well-rested and prepared. Approximately 80% of candidates are successful on their first exam attempt.

Exam Scheduling and Testing Procedures

The Academy offers a 10-day testing window in both March and September. Eligible candidates receive an Eligibility Notice which includes instructions for scheduling a personal exam appointment at <http://www.prometric.com/acrp>. Candidates will be able to select the testing center, exam date, and time. Only candidates determined to be **ELIGIBLE** will receive this important eligibility notice and be able to schedule an appointment.

Rescheduling Exam Within Same Exam Cycle

Rescheduling your exam appointment (test center location, date, or time) is permitted by Prometric **up to 5 days before your scheduled day** by contacting Prometric directly at 800-853-6769. There may be fees associated with appointment changes.

Rescheduling Exam Appointments		
Time Before Appointment	Prometric Fees	Method
More than 30 days before scheduled appointment	No charge	Online or via phone
29 – 16 days before scheduled appointment	\$25	Online or via phone
15 – 5 days before scheduled appointment	\$50	Online or via phone
Less than 5 days before scheduled appointment	Not permitted – full Exam fee forfeited	
Rescheduling Due to Emergency	See Policy below	Emergency Exam Cancellation Form sent to the Academy
Failure to Appear for Scheduled Exam	All fees forfeited	

Emergencies

If a candidate will be unable to keep their exam appointment due to an emergency situation that arises within five (5) days prior to their exam date, the candidate is required to submit an [Emergency Cancellation Form](#) and official documentation to the Academy at certification@acrpnet.org documenting the emergency. This information should be received by the candidate's scheduled exam date or no more than seven (7) days after the scheduled exam date. The following situations will be considered:

- Emergency room visit or hospitalization
- Severe medical condition requiring hospitalization
- Death of an immediate family member (spouse, child/dependent, parent, grandparent, sibling)
- Jury duty
- Call to active military duty

Transfer to Next Exam Window

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

1. If a candidate is determined ineligible for the current exam window, but will have met the eligibility requirements by the next exam window; or
2. If a candidate must withdraw from the exam window originally applied for (up to 5 days before a scheduled exam appointment)

(e.g. Candidate applies and is eligible for the March 2012 exam window but must withdraw; eligibility may be applied towards September 2012 exam only, but not the March 2013 exam window.)

If a candidate wishes to transfer to the next Exam Window for one of the two reasons above, the candidate must complete an [Exam Transfer Request Form](#) before the end of the Exam Window for which the candidate originally applied.

If a transfer candidate does not submit the [Exam Transfer Request Form](#) before the end of the Exam Window for which the candidate originally applied, then all funds originally submitted will be forfeited.

Transfer of eligibility and associated fees will only be applied to the original candidate and are not transferable to another person, even if paid for by a third party. Exam Fees associated with transferring may only be used towards the next exam and not towards other products or services.

If the candidate paid the member price originally, but his or her membership is expired when applying for the next exam, the candidate is responsible for the membership fee or the difference in the standard exam rate versus the member rate.

If the exam fee increases from one cycle to the next, the original exam fee submitted will be honored unless membership fees or the difference between the standard and membership rates is due.

Reactivation Form

Once a candidate has indicated his/her interest in transferring to the next testing window, he or she must submit a Reactivation Form to signal his/her intent to test. The Reactivation Form must be submitted by the regular deadline for the next testing window. **Reactivation Forms** are emailed at the start of the next Exam application period and are addressed to confirmed Transfer candidates only.

If a candidate who has transferred his/her eligibility does not submit a Reactivation Form by the regular deadline, the candidate will forfeit all fees.

Cancellations

Cancelling your exam appointment (test center location, date, or time) is permitted by Prometric **up to 5 days before your scheduled day** by contacting Prometric directly at 800-853-6769. There may be fees associated with appointment cancellations.

Cancelling Exam Appointments		
Time Before Appointment	Prometric Fees	Method
More than 30 days before scheduled appointment	No charge	Online or via phone
29 – 16 days before scheduled appointment	\$25	Online or via phone
15 – 5 days before scheduled appointment	\$50	Online or via phone
Less than 5 days before scheduled appointment	Not permitted – full Exam fee forfeited	
Cancellations Due to Emergency	See Policy below	Emergency Exam Cancellation Form sent to the Academy
Failure to Appear for Scheduled Exam	All fees forfeited	

Note: See Refunds section below. The Academy does not refund fees for exam cancellation requests received less than 5 days prior to the scheduled exam.

To cancel an exam appointment it is mandatory that the candidate **FIRST** contact Prometric directly at 800-853-6769 and then contact the Academy at Certification@acrpnet.org. **Only the candidate may request a cancellation, regardless of whether the exam fee was paid by the candidate or another party.**

If the candidate has not yet scheduled the exam appointment with Prometric, it is mandatory that the candidate submit an [Exam Transfer Request Form](#) or request a refund by the end of the Exam Window for which the candidate originally applied. Exam Fees are non-refundable for requests received after the close of the Exam Window.

Emergencies

If a candidate will be unable to keep their exam appointment due to an emergency situation that arises within five (5) days prior to their exam date, the candidate is required to submit an [Emergency Cancellation Form](#) and official documentation to the Academy at certification@acrpnet.org documenting the emergency. This information should be received by the candidate's scheduled exam date or no more than seven (7) days after the scheduled exam date. The following situations will be considered:

- Emergency room visit or hospitalization
- Severe medical condition requiring hospitalization
- Death of an immediate family member (spouse, child/dependent, parent, grandparent, sibling)
- Jury duty
- Call to active military duty

Refunds

If a candidate must cancel an exam, the **ONLY** portion of the total amount submitted that will be refunded is the Exam Fee provided that the request for cancellation is received at least 5 calendar days prior to a scheduled exam appointment. Cancellation requests received after that time will not be refunded. No refunds are available to candidates who do not attend the exam. Refund requests will only be accepted if made by the candidate.

Applications who do not meet the eligibility requirements for the exam (are **ineligible**), or who are ineligible due to an **incomplete** application, will receive a refund of the exam fee ONLY.

Refund requests can only be made by the candidate. The refund 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 the payment was made by check, the Academy will mail a refund check to the original payer.

Test Center Selection

Candidates can visit <http://www.prometric.com/acrp> at any time to view test centers in the Prometric testing center network.

When an eligible candidate goes online to schedule his/her exam appointment, a specific testing center must be selected.

For assistance with selecting your test center, view this document:
<http://www.acrpnet.org/PDF/ExamSites.pdf>.

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 special needs have been addressed:

- Wheelchair access is available at all established test centers.
- Candidates with visual, sensory, 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, check the appropriate box on the application. See Appendix 2 of this guide to obtain the [Special Accommodations Form](#). A link to the Special Accommodations form is also available on both the online and printable applications. Complete and submit **with** your application.

Exam Schedule and Admission Details

Identification: Exam candidates will be required to present two (2) forms of valid and non-expired identification at the test center. The primary form of identification must be a current government-issued picture ID (e.g., driver's license or passport). A second form of ID must also be presented and must include a signature (e.g., credit card or marriage license).

The candidate's First and Last name as it appears on the exam application must match the First and Last name on the primary and secondary forms of identification. If the First and Last name listed on the application is not correct, contact the Academy office immediately (before the test appointment) at Certification@acrpnet.org.

Candidates will not be admitted to the exam without proper identification. If a candidate arrives at the test center without proper ID, the appointment will be forfeited and the candidate will be required to reapply and repay fees to take the exam.

Time: The times, dates, and locations of the exams are available when the candidate makes the test appointment. It is the candidate's responsibility to arrive on time. 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 test. The candidate will be permitted to reschedule during that testing period as long as there is sufficient time to reschedule and the site is available. An additional charge of \$50 will be incurred and should be paid directly to Prometric. No refunds will be given if the exam cannot be rescheduled.

Including check-in time, pre-exam procedures (computer tutorial), exam, and post-exam evaluation, be prepared to stay at the exam site 3½ to 4 hours.

- **Length of the Exam:** All *Certification* exams have a time limit of three hours from the time the exam is started.
- **Supplies Needed:** An online calculator will be available at the test center and a whiteboard will be provided for comments. Candidates can request a hand-held calculator which will be provided by the test center. Study aids are not permitted. Non-electronic strict translation dictionaries are permitted but will be examined both before and at the end of the exam. Use of dictionaries is discouraged as this uses valuable test time.
- **Visitors:** No visitors will be allowed in the test center.
- **Room Temperature:** It is advised to dress in layers to prevent being too hot or too cold during the exam.
- **Computer Issues:** If any issues arise, notify the proctor immediately (e.g., calculator malfunction, exam stops prematurely, etc.)
- **Noise:** Candidates will be testing in a room with other candidates who may be taking other types of professional exams. The test center will have available noise cancelling headphones, which a candidate can request if desired. You cannot bring your own.

Exam Security

Exam content will be transported via encrypted electronic file to each exam site to ensure the security of the exam questions. Computer-based testing allows for different versions of the exam to be offered and for changes in the sequence of questions to reduce the likelihood of misconduct, and enhances the validity and integrity of the exam. Each exam will be delivered via individual video-monitored testing carrels -- both for better privacy while the candidate is taking the exam and to prevent unethical behavior.

Examinees will be presented with Prometric Testing Center Regulations upon arrival at the test site. It is imperative to read the information provided, because those who violate security will not have their exams scored or processed, and will be required to leave the room immediately. To view regulations in advance, visit <http://www.prometric.com/TestTakers/FAQs/default.htm>.

Removing or attempting to remove exam material or content from the testing center will result in severe criminal and civil legal consequences.

Test Taking Strategies

Most adults haven't taken a standardized exam recently. It can be helpful to be reminded of some key strategies for how to approach a multiple-choice exam:

- Read the entire question before you look at the answer.
- Come up with the answer in your head before looking at the possible answers, this way the choices given on the test won't throw you off
- Eliminate answers you know aren't right.
- Read all the choices before choosing your answer.
- There is no guessing penalty, so it's always best to take an educated guess and select an answer.
- Don't keep on changing your answer, usually your first choice is the right one, unless you misread the question.
- Go through the exam and answer the questions you know first. Mark the others for review and then go back to those you skipped over. This will make sure you don't lose time by focusing on one question you aren't sure about.

Exam Results

Computer-based testing provides participants with preliminary results immediately, with official confirmation of results following within 30 days. On-site notices are preliminary and candidates ***are not yet considered certified until official notification is received from the Academy.*** Candidates who pass the exam will be sent an official notice of *Certification*, a certificate, a CCRA® pin, and *Maintenance of Certification* information.

Candidates who do not pass the exam are advised to review the content area scores and use this information to assist them 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. Candidates who pass the exam will be added to the Academy *Certification* registry unless they opt out. The Registry can be accessed at <http://www.avectraacrp.com/eWeb/DynamicPage.aspx?Site=ACRP&WebKey=078ec803-bceb-4265-9ca4-81780725fa6e>

Duplicate Certificates

There is a \$25 charge for a duplicate certificate if the request is made more than three months after the exam. Requests may be made in writing by completing the [Duplicate Certificate Form](#) to ACADEMY at Certification@acrpnet.org.

Maintenance of *Certification* by Continuing Education/Continuing Involvement

Once a candidate has achieved *Certification*, it is valid for two (2) years. In order to continue to be certified and to continue to use the designation after two (2) years, certificants will need to apply for Maintenance of Certification.

The Academy requires periodic *Maintenance of Certification* to ensure that individuals who hold a CCRA®, credential maintain their ongoing commitment to professional development in their selected area of practice. Through the *Maintenance of Certification* requirements, certificants demonstrate expansion and reinforcement of their knowledge of current practice.

The Academy supports this purpose by requiring appropriate and relevant continuing education activities to enhance the professional development of certificants. The *Maintenance of Certification* program also serves to encourage and recognize individuals who participate in ongoing professional development.

CCRA®s must maintain every two (2) years from the time of original *Certification*. The two year *Maintenance of Certification* cycle is based on the frequency of change in the clinical research field. *Maintenance of Certification* requires the completion of 24 documented hours and/or points. These points can be earned through traditional education contact hours or through continuing involvement.

Requirements:

To maintain *Certification* successfully, CCRA® certificants must:

1. Satisfy the requirements of either Option 1 or Option 2 listed below.
2. Document the hours/points on the *Maintenance* application (online or printable form).
3. Submit completed application together with appropriate payment by expiration date*.

*Incomplete submissions will be charged the late fee if not rectified by the expiration date.

Option 1 – Contact Hours Only:

Maintenance of Certification by continuing education requires the completion of 24 documented continuing education contact hours within the appropriate timeframe, with at least 12 of those hours being in clinical research topics. The remaining hours claimed to make up the 24 hour requirement must be from healthcare related courses (therapeutic topics).

OR

Option 2 – Contact Hours and Continuing Involvement:

Maintenance of Certification may also be achieved by the completion of a total of 24 documented points; a maximum of 12 continuing involvement points (see chart below) **and** 12+ continuing education points (a minimum of 8 points (for this option only) must be in clinical research topics)*.

CCRA® Maintenance Requirements 24 points Total Needed		
Activity	Number of Points Each	Maximum Points <u>Allowed</u> in Category
Continuing Education Clinical Research Topics	1 point for each hour of instruction	24
Continuing Education Therapeutic Topics	1 point for each hour of instruction	12
Continuing Involvement Item Authoring a journal article on Clinical Research Topics	4	8
Continuing Involvement Item Preparing/presenting a 1-3 hour presentation on Clinical Research Topics	3	6
Continuing Involvement Item Authoring/presenting a half-day workshop on Clinical Research Topics	6	12
Continuing Involvement Item Authoring/presenting a one-day workshop on Clinical Research Topics	12	12

Revocation of *Certification*

The Academy may revoke *Certification*, or take other disciplinary or legal action, in the case of falsification or the provision of misleading or incomplete information in the CV or statement of experience. ACRP may also revoke *Certification*, or take other disciplinary or legal action, in the event that an individual is in violation of the ACRP/APCR Uniform Code of Ethics and Professional Conduct or has regulatory or professional restrictions placed on his or her clinical research practice or professional license. ACRP will adhere to due process principles. If a certificant is notified of revocation, he or she will also be notified of the appeal process. Copies of the Discipline and Complaints Policy and Appeals Policy may be requested by contacting the ACRP office in writing.

How Are *Certification* Exams Developed?

In response to the ACRP membership's numerous requests for professional recognition, two exam committees were established in 1990; by 1992, the first *Certification* exams were developed with the assistance of a professional testing organization. The Exam Committees—one each for CRAs and CRAs—identify areas of competency for testing, develop appropriate test questions, and assist with validation of the exams.

It is important to note that The Academy's programs are accredited by the National Commission for Certifying Agencies (NCCA). NCCA sets internationally-recognized standards for the development and operation of certification programs. The standards assure that a program is valid, reflects current practice and is fair to candidates.

The development of certification examinations begins with a Job Analysis. A job analysis is a survey that goes to members of a profession to create a definitive description of the tasks required to perform a job role and the knowledge needed in order to complete those tasks. A Job Analysis Survey is typically conducted every 5-7 years to assure the exam is testing current practice in a job role.

In 2010, the Academy updated its CRA job analysis with a survey sent to thousands of clinical research professionals. 3,636 responded to the survey. The results of the survey identified for the Academy what to include on the Detailed Content Outlines (DCOs) for each job role. Those task and knowledge statements that the majority of CRAs said were essential to their job role and performed frequently are covered on the exam. The results are then incorporated into the CRA *Detailed Content Outline*.

Individuals who are already certified as a CRA are then trained to write test questions. We call these volunteers "Subject Matter Experts" or "SMEs". All questions must test knowledge and skills as defined by the Detailed Content Outline (DCO). All test questions must be referenced to specific areas of ICH Guidelines, as described in our candidate guides. Once the SMEs write draft questions, they go to the CCRA® Exam Committee for review. This process is constantly in motion, with new questions being written, current questions being reviewed, and older or non-performing questions being "retired" from the item bank.

The CCRA® Exam Committee is made up of a separate group of currently practicing, certified CRAs who review, edit, discuss, and re-write the draft test questions. Many draft test questions are discarded in the process. Others still are completely re-written or heavily edited. Each question must meet minimum standards for applicability to the job role. All Exam Committee members must agree that the answer keyed as correct is, in fact, the only correct answer possible.

Once a draft question is approved by the Exam Committee, it then becomes a pre-test question. All questions are pre-tested before they are counted toward a candidate's score. The exams given to candidates are 125 questions long. 100 of those questions are count toward the candidate's score. 25 are pre-test questions. This means the Academy is collecting statistical data on the items to see if they are well constructed enough to appear on the exam as a scored item. Hundreds of candidates answer a pre-test question before it can be determined if it can be used toward a candidate's score.

Once enough data has been collected, analyses are performed on the item statistics in conjunction with the Academy's professional test development partner to see if items have performed well enough to be used. If they have not performed well, (for example, many are choosing the wrong answer; or each of the four answers is being selected equally which indicates test-takers are guessing; or candidates who score well on the exam overall are selecting a wrong answer), then the questions is set aside for further review and re-write or possibly discarded. Only those questions that demonstrate they are fair to the test taker and identify proficiency in a candidate are used.

Several diverse groups of CRA volunteers are used to write the questions, review the questions, select questions to be pre-tested and to select and review questions that actually appear on the exam. The Academy follows a process that meets international standards for test development and works with a highly-regarded testing partner.

To date, more than 24,000 clinical research professionals have been *Certified* by the Academy. On average, 80% of those who sit for an exam pass the exam.

Exam Results by Program 2008 - 2011

CRC Exam								
	Sep-11	Mar-11	Sep-10	Mar-10	Sep-09	Mar-09	Sep-08	Mar-08
Took Exam	622	515	603	417	602	539	721	559
Total Certified	452	388	491	325	482	416	571	430
Percent Passing	72.7%	75.34%	81.42%	77.93%	80%	77.17%	79.19%	76.92%

CRA Exam								
	Sep-11	Mar-11	Sep-10	Mar-10	Sep-09	Mar-09	Sep-08	Mar-08
Took Exam	362	282	448	336	450	415	501	371
Total Certified	236	208	325	244	335	298	389	294
Percent Passing	65.19%	73.76%	72.54%	72.62%	74.44%	71.81%	77.64%	79.25%

CPI Exam								
	Sep-11	Mar-11	Sep-10	Mar-10	Sep-09	Mar-09	Sep-08	Mar-08
Took Exam	42	30	58	36	54	65	103	63
Total Certified	35	24	50	28	38	54	84	57
Percent Passing	83.33%	80%	86.20%	77.78%	70.37%	83.08%	81.55%	90.48%

All Programs								
Percent Passing	70.47%	74.97%	78.09%	75.60%	77.30%	77.35%	79.46%	82.22%

Reliability Measurements

After every *Certification* exam, the Exam Committees review the results with the assistance of Prometric, one of the testing industry's leading firms. Each item is analyzed for appropriate psychometric characteristics. Those items with poor statistical results are reviewed by the appropriate Exam Committee to ensure that they have been scored properly. Participant feedback regarding the exam and its contents is also reviewed and taken into consideration when reviewing the exam and future test items.

FREQUENTLY ASKED QUESTIONS

How will I know if my exam application was received?

An email confirmation is automatically sent once payment is processed. Applicants will also be sent an email that confirms that the application was received by the Academy. PLEASE NOTE: These confirmations do not confer eligibility. A separate notification will be sent regarding an eligibility decision. Please take any necessary steps to prevent filtering of ACRP emails.

How will I know if I am eligible to take the exam?

Once processing of exam applications has begun, an email will be sent within three weeks after receipt of the application, notifying you of your eligibility status or any deficiencies that may exist.

What should I bring to the test center?

Bring two forms of appropriate identification, as described in this Guide. Online calculators will be provided.

What happens if I need to cancel the exam?

If a candidate has already scheduled an appointment with Prometric, then:

1. Contact Prometric to cancel the appointment, at 800-853-6769
2. Pay the appropriate cancellation fee to Prometric (if applicable)
3. Notify the Academy in writing at Certification@acrnet.org once the appointment is cancelled

If the candidate has not yet scheduled an appointment with Prometric, then the candidate should notify the Academy in writing at Certification@acrnet.org.

If you cancel at least 5 days prior to the exam, you will receive a refund of the exam fee ONLY. No refunds are available fewer than 5 days prior to the exam.

What if I need to retake the exam?

An exam may only be attempted once during each testing window. Candidates who have failed the exam may reapply and retake the exam during the next available testing window.

What happens if I miss the application deadline?

All applications must be *received* by the Academy (not postmarked) by the application deadline. Faxed applications will be accepted. If you miss the deadline, you will have to wait until the next scheduled exam date. Your application will not be returned to you.

What tools does ACRP have available to help me prepare for the exams?

As noted earlier in this Guide, the Detailed Content Outline (DCO) and therefore the content of the CCRA exam, has been updated for exams beginning in 2012.

ACRP's Professional Development program is currently in the process of developing CRA role-specific guides to assist candidates in reviewing concepts that may be found on the exam. It will be available for purchase in January 2012.

In addition, beginning in January 2012, a new Candidate Self- Assessment, which is made up of job-role specific test questions retired from previous exams will also be available for purchase. These questions are designed to be representative of those you will see on the exam and to familiarize yourself with the format of the exam, but should not be used to identify areas for additional study.

For further information, please visit <http://www.acrpnet.org/examprep>

What is the Academy's *Maintenance of Certification* process?

The Academy requires periodic *Maintenance of Certification* to ensure that individuals who hold a CCRA[®] credential maintain their ongoing commitment to professional development in their selected area of practice. Through the *Maintenance of Certification* requirements, certificants demonstrate expansion and reinforcement of their knowledge of current practice.

The Academy supports this purpose by requiring appropriate and relevant continuing education activities to enhance the professional development of certificants. The *Maintenance of Certification* program also serves to encourage and recognize individuals who participate in ongoing professional development.

CCRA[®]s must maintain every two (2) years from the time of original *Certification*. The two year *Maintenance of Certification* cycle is based on the frequency of change in the clinical research field. *Maintenance of Certification* requires the completion of 24 documented continuing education contact hours. A minimum of 12 of the 24 hours completed **MUST** be in clinical research topics. Effective January 1, 2010, *Maintenance of Certification* may also be achieved by completion of a total of 24 documented points, with a maximum of 12 points of continuing involvement activities according to the schedule below:

- Authoring a journal article – 4 points per article – 8 points maximum
- Preparing/presenting a 1 hour presentation – 3 points per presentation – 6 points maximum*
- Authoring/presenting a ½ day workshop – 6 points per workshop – 12 points maximum*
- Authoring/presenting a 1 day workshop – 12 points per workshop – 12 points maximum*

**Points may only be claimed one time regardless of how many times the same program is presented.*

Continuing education contact hours must be used to complete the 24 point requirement if the full 12 points of continuing involvement are not used.

If continuing involvement activities are used for maintenance, of the remaining points earned through continuing education a minimum of 8 continuing education contact hours must be in clinical research topics.

What records of continuing education or continuing involvement activities should I keep?

Copies of certificates should not be submitted with the maintenance submission. Certificants should retain all certificates with their records in case of selection for a random verification. The Academy will request these records if needed. All continuing education activities submitted for *Certification* maintenance are subject to review and approval. The Academy reserves the right to request additional information and to verify any documentation, including academic records. Credit may be denied for continuing education activities that fail to meet the guidelines established in this policy.

What type of contact hours can I use to maintain?

The *Maintenance of Certification* Guide explains that acceptable courses for earning continuing education contact hours include those offered by:

- All state and national nursing associations;
- American Council on Pharmaceutical Education (ACPE);
- Accreditation Council for Continuing Medical Education (ACCME); and
- Other national healthcare-related associations (respiratory therapy, medical technician, etc.).

What are examples of unacceptable continuing education contact hours?

Attendance certificates for programs that do not offer continuing education contact hours with a provider number.

- CPR or BLS training courses
- Blood pressure training courses
- Investigator meetings that don't offer contact hours
- Courses that focus on self-improvement, changes in attitude, computer skills, investments, and liberal arts

What happens if I do not maintain my *Certification*?

Individuals who fail to properly maintain their *Certification(s)* will be decertified for failure to maintain by the specified deadline. You will receive a 2-week grace period in which you may maintain with payment of a late fee and submission of the required continuing education credits/continuing involvement. If you do not respond by the end of the grace period, you will be decertified and will receive notification of this action.

Can I reinstate my *Certification* if it has expired?

A certificant who has had a credential revoked due to not meeting the *Certification* maintenance requirements may re-apply for *Certification*. The individual must meet the current eligibility requirements, pay all required fees, and successfully pass the exam.

NON-DISCRIMINATION POLICY

It is ACRP/APCR's philosophy and policy to avoid discrimination based on race, color, national origin, sex, age, religion, marital status, sexual orientation, or other status or condition that is protected by applicable law.

CONFIDENTIALITY

The Academy protects the confidential information of applicants and certificants. In addition to personal information submitted in the application, exam results are also considered confidential. Unless otherwise required by law, confidential information will only be released to the individual applicant/certificant unless a signed release is provided.

VERIFICATION OF CREDENTIALS

An individual's *Certification* status may be verified through the searchable Academy registry on the ACRP website. Requests for written verification may be requested by contacting the Academy office and will require a signed release from the certificant.

CERTIFICATION MARK USE

The Academy grants limited permission to individuals who have met all of the *Certification* eligibility criteria, passed the exam, and received notification of *Certification* from the Academy to use the *CCRA*[®] designation that has been granted to them.

Use of the *CCRA*[®] credentials by individuals who have not been granted *Certification*, or who have failed to properly maintain *Certification* in good standing, is prohibited. Improper use of the credentials or *Certification* marks may result in disciplinary or legal action.

The *CCRA*[®] designation is federally registered intellectual property of ACRP, and use of the designations and *Certification* marks is subject to approval by ACRP.

DISCIPLINE AND COMPLAINTS POLICY

ACRP enforces the ACRP/APCR Uniform Code of Ethics and Professional Conduct for all CRA, CRA, CTI, and PI certificants and individuals in the process of obtaining CRA, CRA, CTI, or PI *Certification*.

ACRP will investigate reported violations of the Uniform Code of Ethics and Professional Conduct. Complaints regarding alleged violations should be reported to ACRP in writing and should include a detailed description of factual allegations supporting the charges and any relevant supporting documentation.

Information submitted during the complaint and investigation process is considered confidential and will be handled in accordance with ACRP's Confidentiality policy. ACRP adheres to due process principles. Adverse disciplinary decisions made by ACRP (or its committees) may be appealed. A complete copy of the Discipline and Complaints policy and procedure and the Appeal policy and procedure may be requested by contacting ACRP.

APPENDIX 1 – SAMPLE CV

Betty Smith, R.N., B.S.N.
233 ABC Drive
Arlington, VA 22314
703-555-1111

Education:

XYZ State University
Bachelor of Science in Nursing
August 2003

Clinical Research Education – only required if claiming completion in lieu of 1 year of CRA experience

Name of School – CCC, **Program Title:** ABCs of Clinical Research, **Name of Organization that Accredits the Educational Institution Providing this Program** – Accrediting Bureau of Health Education Schools, **Dates Attended – From – To** – 10/07 – 10/08

Professional Experience:

Clinical Research Associate
JKL Hospital
Research Department

12/1/2005 to present

Job Duties:

- Assists with investigational study selection and project negotiation, including initial site/sponsor correspondence, budget preparation, regulatory document preparations for protocol, informed consent and appropriate HIPPA inclusions for IRB submission.
- Ongoing management of study review process according to site/sponsor/IRB guidelines.
- Responsible for patient screening, recruitment, consent process and enrollment for ongoing clinical research projects, including all follow up management visits and case report form completion.
- Maintains source documentation and drug/device accountability.
- Conducts staff in-services prior to implementation of new research trials.

Cardiovascular Nurse Clinician / Clinical Research Associate
University of XYZ Medical Center
Division of Cardiovascular Diseases

6/22/2004 to 11/30/2005

Job Duties:

- Responsible for managing protocols, patient consent forms, patient screening, source documents, recruitment and follow up management.
- Completed case report forms and regulatory documents.
- Participated with physician on hospital rounds and discharge teaching.
- Performed noninvasive exercise and echocardiographic exercise testing.



Special Accommodations Request Form

GLOBAL HEADQUARTERS
500 Montgomery St.
Suite 800
Alexandria, VA 22314 USA
www.acrpnet.org

T) 703-254-8100
F) 703-254-8101
office@acrpnnet.org

Please have this form completed by an appropriate, licensed health professional to ensure that Prometric is able to provide a reasonable examination accommodation. The information you provide and any documentation regarding your disability and your need for accommodation in testing will be treated with strict confidentiality.

Please submit this form with your *Certification* application or fax to 703-254-8102
Attn: Certification Program
by **January 23, 2012**

Professional Documentation:

I have known _____ since _____ in my
Exam Candidate *Date*

capacity as _____ (Professional title). The candidate discussed with me the nature of the examination to be administered. It is my opinion that because of this candidate's disability described below, he/she should be accommodated by providing the special arrangements indicated below.

Disability: _____

Please check all that apply:

- Extended testing time:
 - ½ hour 1 ½ hour 3 hours
- Enlarged text
- Other (describe):-

Accommodation is being requested for the ___ CCRASM ___ CCRCSM ___ CPISM

Exam location _____ (city, state, country)

Print Name _____ Phone _____

Signed _____ Date _____



March 2012 Exam Transfer Request Form

Must be received by the Academy by 10 March 2012

The Academy offers a one-time transfer of an applicant's application from one exam cycle to the next.

There are two situations in which applicants may take advantage of this option:

1. If an applicant is determined Ineligible for the current exam window, but will have met the eligibility requirements by the next exam window
2. If an applicant is determined Eligible, but must withdraw from the exam window (*up to 5 days before a scheduled exam appointment time*)*

If you wish to transfer your application, you may transfer to the next exam cycle **only**. All fees will become non-refundable. If for any reason you are unable to take the exam during our next exam cycle, all fees will be forfeited.

***You must cancel your exam appointment with Prometric testing centers before submitting this form.**

Please note that if you paid the Member Rate for the exam, you will need to keep your Membership current for the next exam cycle. If your Membership expires before the next exam cycle, you will need to renew your Membership, or pay the difference between Member and Standard Exam Fees.

Candidate Name (printed): _____

Name of Exam: _____

Reason for Transfer: _____

- I have read the [Transfer Terms & Conditions](#) page
- I have canceled my exam appointment with Prometric (if one was scheduled) at 800-853-6769.

Candidate Signature: _____ Date: _____

Please e-mail this form to certification@acrpnnet.org, or fax it to 703-254-8102 by **10 March 2012**.



Emergency Exam Cancellation Form

To be completed within seven (7) days

GLOBAL HEADQUARTERS
500 Montgomery St.
Suite 800
Alexandria, VA 22314 USA
www.acrpnet.org

T) 703-254-8100
F) 703-254-8101
office@acrpnnet.org

Usually, if a candidate does not cancel his/her scheduled exam appointment at least five (5) days prior to the scheduled date, or does not appear for the exam as scheduled, he/she forfeits all fees. However, if a candidate will be unable to keep their exam appointment due to an emergency situation that arises within less than five (5) days prior or the day of the scheduled exam appointment date, the Academy may consider waiving the forfeited fee.

In order to be considered for such a waiver, the candidate is required to submit the **Emergency Exam Cancellation Form** along with accepted, official, supporting documentation of the emergency to the Academy at certification@acrpnnet.org. This information should be received by the Academy before the candidate's scheduled exam date or as soon as the emergency has passed but no later than seven (7) days after the scheduled exam date.

The following situations will be considered:

- Emergency room visit or hospitalization
- Severe medical condition requiring hospitalization
- Death of an immediate family member (spouse, child/dependent, parent, grandparent, sibling)
- Jury duty
- Call to active military duty

Notification and documentation of the emergency must be submitted by the candidate to the Academy no later than seven (7) calendar days past the scheduled exam date.

Email this form and corresponding documentation to the Academy at certification@acrpnnet.org
NO LATER THAN SEVEN (7) DAYS AFTER A SCHEDULED EXAM DATE. Fax is also accepted- 703.254.8102.

Candidate Name: _____

Date of Missed Exam: _____

Reason: _____

Supporting Document Type Attached (e.g. Emergency room release, death certificate):



Duplicate Certificate Request Form

GLOBAL HEADQUARTERS
500 Montgomery St.
Suite 800
Alexandria, VA 22314 USA
www.acrpnet.org

T) 703-254-8100
F) 703-254-8101
office@acrpnnet.org

Those currently holding a *Certification* through the Academy may request a duplicate copy of their certificate. A \$25.00 USD fee will be charged if the request is made more than three (3) months after the original certificate was issued. If you would also like a copy of your certificate faxed or e-mailed to you, please indicate that below.

*These requests can **only** be made by the current certificant.*

Please select all that apply:

- I am requesting a duplicate certificate, and include my address and payment information below.
- I am requesting that a duplicate certificate also be ***faxed****
- I am requesting that a duplicate certificate also be ***e-mailed****

Certificant Name (printed): _____

Certificant Signature: _____ Date: _____

*Fax Number or E-mail Address: _____

Mailing Address: _____

City: _____ State: _____ Zip code: _____

Payment Information

METHOD OF PAYMENT: Check MC Visa AMEX (circle one)

Credit Card Number: _____ Expiration Date: _____

Total Amount Due \$ _____

Please return to us via e-mail at certification@acrpnnet.org, or fax it to 703-254-8102.