

CRC CERTIFICATION GUIDE



ACRP
ASSOCIATION OF CLINICAL
RESEARCH PROFESSIONALS

Association of Clinical Research Professionals | 500 Montgomery St., Suite 800 | Alexandria, VA 22314 | www.acrpn.net



The Academy's CRC and CRA *Certification* programs are accredited by the National Commission for Certifying Agencies (NCCA), the accrediting body of the Institute for Credentialing Excellence (formerly the National Organization for Competency Assurance created in 1977). For more information on accreditation, visit www.credentialingexcellence.org/ncca.

CERTIFICATION CHECKLIST

Before you begin the certification application process, be sure to:

1. Read the entire CRC 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 acrpnnet.org to verify your member status. If you want to join before applying for your exam, join online at acrpnnet.org. Once you join, logout of acrpnnet.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 specific documents in order for your application to be considered. Documentation required for CRC Candidates 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 email confirmation of receipt within 10 business days (longer for mailed or faxed applications). All applications must undergo a thorough review process. Please allow for up to 3-4 weeks for your eligibility email notification. To ensure you receive your notification, we recommend you add acrpnnet.org to your safe senders list (contact your local IT department for instructions).

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QUICK REFERENCE QUESTIONS

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

Question	Contact ACRP or Prometric?	Contact Information
Exam Registration Questions		
Exam Application Received?	ACRP Member Services	office@acrpnet.org
Didn't Receive Notification of Eligibility	ACRP Certification	certification@acrpnet.org
What is my Prometric Testing ID Number?	ACRP Certification	certification@acrpnet.org
Test Sites	Prometric website	www.prometric.com/ACRP or www.prometric.com/APPI
Exam Fees	ACRP website – Fees calculator	www.acrpnet.org
Exam Rescheduling (within same testing window only)/Cancellations		
Exam Rescheduling or Cancellation greater than 29 days prior to exam	ACRP	certification@acrpnet.org
Exam Rescheduling or Cancellation 16 -29 days prior to scheduled exam	Both: Prometric first to pay \$25 and then notify ACRP in writing	800-853-6769 certification@acrpnet.org
Exam Rescheduling 5-15 days prior to scheduled exam (no cancellations permitted less than 15 days prior)	Both: Prometric first to pay \$50 and then notify ACRP in writing – no refunds permitted	800-853-6769 certification@acrpnet.org
No rescheduling permitted less than 5 days prior to exam date	ACRP	certification@acrpnet.org
Post Exam Questions		
Change of Contact Information	ACRP Member Services	office@acrpnet.org
Hand Score Requests	Prometric	800-481-6525
General Contact Information		
Prometric Member Services	Prometric	800-481-6525
To report issues with your Prometric experience	Prometric	800-853-6769
ACRP	Certification Department	500 Montgomery Str, Suite 800 Alexandria VA 22314-1560 Phone: 703-254-8100 Fax: 703-254-8101 Email: certification@acrpnet.org

GENERAL INFORMATION

What is Certification?

ACRP/APPI certification is the formal recognition of clinical research professionals who have met the professional eligibility requirements and demonstrated job-related knowledge and skills.

Certification is granted in recognition of documented and verified work experience, education and after successful performance on a multiple-choice exam.

How Were Certification Exams Developed?

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

A Job Analysis Survey, examining 138 work-related tasks, was distributed to over 1,300 CRCs. ACRP's CRC Job Analysis Committee reviewed the results, determined the most significant tasks, and incorporated those results into the CRC content domain. The CRC Exam Committee then identified areas of competency for testing from the content domain and wrote the test questions targeting those areas.

An online Job Analysis Survey, examining 134 work-related tasks, was distributed to over 1,300 clinical research associates. ACRP's CRA Job Analysis Committee reviewed the results, determined the most significant tasks, and incorporated them into the CRA content domain. The CRA Exam Committee then identified areas of competency for testing from the content domain and wrote the test questions targeting those areas.

In 2000, the ICH Physician Investigator Exam Committee was formed in order to develop an exam for clinical trial investigators in Europe. The exam was first held in December 2001. A similar Exam Committee was established in North America and the first exam was held in April 2002. In July 2005, ACRP's Certified Clinical Trial Investigator (CCTI) designation was changed to CPI for physician investigators; it remained CCTI for non-physician investigators as part of ACRP's affiliation with the American Academy of Pharmaceutical Physicians & Investigators (AAPP). The physician group was renamed as the Academy of Pharmaceutical Physicians & Investigators (APPI). In 2006, ACRP and APPI acquired the certification program from the Drug Information Association (DIA) and assimilated their physician and non-physician certificants into the ACRP/APPI programs.

To date, there have been over 8,000 CRAs, 15,000 CRCs, 59 CTIs and 925 CPIs to pass the exams. On average, 80% of those who sit for an exam will pass the exam (see next page for full statistics).

Exam Statistics					
CRC Exam	3/2010	9/12/2009	3/7/2009	9/6/08	3/8/08
Took Exam	417	602	539	721	559
Total Certified	325	482	416	571	430
Pass/Fail Rate	77.93	80.00	77.17	79.19	76.92
CRA Exam	3/2010	9/12/2009	3/7/2009	9/6/08	3/8/08
Took Exam	336	450	415	501	371
Total Certified	244	335	298	389	294
Pass/Fail Rate	72.62	74.44	71.81	77.64	79.25
CPI Exam	3/2010	9/12/2009	3/7/2009	9/6/08	3/8/08
Took Exam	36	54	65	103	63
Total Certified	28	38	54	84	57
Pass/Fail Rate	77.78	70.37	83.08	81.55	90.48
Avg. Pass Rate	75.6	77.30	77.35	79.46	82.22

Benefits of Certification

Certification is increasingly recognized by today's global clinical research industry. Study sites use certification for documentation to sponsors and CROs that the site is professionally managed. Certification assists the public, healthcare professionals and the industry itself by identifying standards for professional practice.

The written CRC examination is a measure of a candidate's knowledge of information needed for the CRC to perform this role effectively and the competent application of that knowledge in the conduct of clinical trials.

Industry Recognition

Those surveyed believed that enhanced professional standing, increased company marketability (for CROs), personal satisfaction, increased knowledge and enhanced recognition by peers and supervisors were the primary anticipated advantages for becoming certified.

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.

ABOUT THE CRC EXAM

CRC Definition

A CRC, regardless of job title, works at a clinical research site under the immediate direction of a principal investigator, whose research activities are conducted under Good Clinical Practice (GCP) Guidelines.

CRCs typically perform tasks such as:

- Site preparation
- Patient screening and recruitment
- Patient enrollment
- Conducting study visits
- Maintaining and dispensing drug supplies
- Completing and ensuring the quality of case report forms
- Maintaining source documents
- Ensuring site quality.

Requirements for Admission to the CRC Exam

To be eligible to take the CRC exam, each candidate must fulfill by the date of the exam one of the following three combinations of education and working experience as a CRC prior to the exam date. A detailed resume or CV (see Appendix 1 for sample CV) and a job description are required and must be included with the exam application. This must include a description of the candidate's roles as a CRC and specific employment dates. The CV that is provided by the sponsor is not sufficient because it does not show job function performance. Do not include a list of study participation on your CV.

Option 1

Education: Associate/Bachelor's degree or RN

Working Experience as a CRC: 2 years full-time, or 4 years part-time, or

Option 2

Education: Other (e.g., LPN, LVN, Medical Assistant, Lab Technician, H.S. diploma)

Working Experience as a CRC: 3 years full-time, or 6 years part-time, or

(Note: A minimum of 37.5 hours per week qualifies as full-time employment, and a minimum of 20 hours per week qualifies as part-time employment)

Substitution of One Year of CRC Work Experience

If a candidate has completed a one-year educational program in clinical research from an accredited institution*, this may be used to substitute one year of the work experience requirements listed in Options 1 & 2. In all cases, a minimum of one year work experience is required.

This substitution requires additional information to be listed on the CV (See Appendix 1 for Sample CV) and the submission of a certificate of completion.

*Organizations that recognize the accrediting agencies of schools:

- Private Sector: <http://www.chea.org/search/default.asp>
- Government (USDE):
<http://www.ed.gov/students/prep/college/diplomamills/index.html?src=rt>
- Foreign Schools: <http://www.aacrao.org/international>

Those candidates who meet the eligibility requirements and pass the exam will be certified as having met ACRP standards for becoming a CCRC[®], as adopted by ACRP. Such certification, however, is neither an endorsement of a particular individual, nor a validation of that person's qualifications for a particular task, and should not be represented as such to third parties.

Employers must be listed on the candidate's application form. ACRP has the right to verify qualifications. A detailed resume or CV must also be included with the application (See Appendix 1 for sample CV). This must include a description of CRC job duties and specific employment dates. The CV that is provided to the sponsor is not sufficient because it does not show job function performance. Do NOT include your list of study participation on your CV.

Language

The CRC Certification Exam is provided in English.

Exam candidates may bring an English-German / Spanish / Dutch / Italian / etc., dictionary to the exam. 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.

CRC Exam Content

ACRP's CRC Certification Exam Committee develops the CRC Exam. The Committee regularly evaluates and improves the existing exam questions, and adds new questions to expand the pool of items.

The exam consists of 125 multiple-choice questions. For each question, candidates are asked to choose the single best answer from the options provided. 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 CRC Certification Exam Committee. The content outline of the CRC exam and the relative distribution of questions are as follows:

Content Outline of the CRC Exam

1. Study Management (15 questions)

- a. Protocol Evaluations
 - i. Assess and identify the protocol and study design
 - a. Phase (i.e., I –IV, pre and post marketing) the protocol is intended to satisfy
 - b. type of study design (e.g., double-blind, crossover)
 - c. compassionate use
 - d. emergency use
 - ii. Follow regulations regarding drugs, biologics, and medical devices

- iii. Assess protocol for clarity, thoroughness, logistical feasibility, maintaining subject safety and welfare, inconsistencies, etc.
- iv. Determine subject population availability
- v. Determine personnel required to complete the clinical trial (e.g., number needed, availability)
- vi. Determine facility and equipment availability
- vii. Develop time lines for conducting and completing the clinical trial
- viii. Identify concerns and questions with the Principal Investigator and Sponsor/CRO (e.g., patient population, Sponsor/CRO expectations, enrollment, study procedures)
- ix. Negotiate alternatives to improve protocol implementation (e.g., inclusion/exclusion criteria, concomitant medications, protocol timelines, logistics)
- x. Review protocol with sponsor/CRO during Investigator's meeting

b. Site Preparation and Initiation

- i. Schedule and coordinate pre-study site visit with Sponsor/CRO's representative
- ii. Prepare regulatory documents for Sponsor/CRO (e.g., investigator agreement, financial disclosure, curriculum vitae, IRB/IEC membership, lab-related documents, delegation of authority, site signature log)
- iii. Prepare recruitment plan
- iv. Prepare and submit IRB/IEC documents
 - a. Informed consent/children's assent form
 - b. Advertisements (e.g., ensure advertisements meet IRB/IEC regulations)
 - c. Protocol and protocol summary
 - d. Investigator's brochure
 - e. Exempt, expedited, or full committee review
- v. Prepare space for study-related equipment and supplies (i.e., storage of study investigational products, laboratory supplies, CRFs/eCRFs)
- vi. Provide instruction to study team for specific study assignments
- vii. Present clinical trial time lines to study team (e.g., enrollment, completion, advertising, schedules)
- viii. Train/educate ancillary staff regarding clinical trial (e.g., pharmacist, medical secretary, medical technician)
- ix. Integrate proposed clinical trial with current research activity
- x. Coordinate study initiation among clinical staff, subjects and Sponsor/CRO

2. Project Activities (45 questions)

a. Investigational Product Accountability

- i. Receive investigational product from Sponsor/CRO and inventory supplies
- ii. Store investigational product supplies according to ICH guidelines
- iii. Prepare/Dispense investigational product according to the protocol (authorized staff only)
- iv. Retrieve investigational product and calculate subject compliance
- v. Order supplemental investigational product
- vi. Return used and unused investigational product to Sponsor/CRO
- vii. Maintain randomization and emergency codes of investigational products (received, used, dispose)

b. Laboratory and Diagnostic Issues

- i. Ensure proper collection, processing, and shipment of specimens (e.g., centrifuge, preparation of slides, freezing, refrigeration)
- ii. Develop procedure and collection forms for laboratory/diagnostic collection and storage
- iii. Communicate laboratory/diagnostic results with Principal Investigator, and Sponsor/CRO
- iv. Maintain regulatory standards for handling dangerous goods
- v. Maintain supply inventory
- vi. Maintain equipment (e.g., calibration and preventative maintenance)
- vii. Ensure proper documentation of equipment maintenance (i.e., logs)
- viii. Recognize common laboratory values and alerts
- ix. Assure current certification/licensure and normal ranges

c. Safety/Adverse Events

- i. Assist the Investigator in determining causality of expected or unexpected results associated with investigational products
- ii. Document adverse medical events
- iii. Implement Investigator's plan of action for management of adverse event (e.g., stop investigational product; call, retest, treat subject)
- iv. Maintain follow-up to determine resolution of adverse event
- v. Report SAE to Sponsor/CRO and Serious Unexpected Association events to IRB/IEC
- vi. Assist Investigator in classifying severity of adverse event (i.e., serious, severe, moderate, mild, expected, unexpected)
- vii. Record adverse event and relevant information on source document, CRF, and Sponsor/CRO specific form

d. Responsibilities and Obligations

- i. Assist the Investigator in the conduct of research in accordance with the statement of Investigator
- ii. Maintain the continuity of the clinical trial while satisfying obligations to the Sponsor/CRO
- iii. Ensure site is prepared for any Regulatory/Sponsor/CRO audits (e.g., consequences, requirements, deficiencies)
- iv. Maintain current knowledge of clinical research issues (e.g., ICH/GCP guidelines)
- v. Implement subject privacy regulations
- vi. Manage research site staff
- vii. Prepare for monitoring visit

e. Close-Out

- i. Determine disposition of study-related materials per Sponsor/CRO requirements
- ii. Reconcile investigational product accountability
- iii. Audit documents and pertinent files and prepare for storage
- iv. Maintain documents as required by ICH guidelines
- v. Prepare/obtain study summary and/or close-out letter for IRB/IEC/Sponsor/CRO
- vi. Provide or verify method of document retrieval from storage
- vii. Document reasons for subject discontinuation (i.e., causes, contact efforts)
- viii. Prepare for and respond to internal and Sponsor/CRO audits, and/or regulatory inspections

3. Subject Coordination (45 questions)

- a. Recruitment Implementation
 - i. Prescreen telephone calls for eligibility requirements
 - ii. Review sources for potential subjects consistent with regulatory requirements (e.g., medical records and databases)
 - iii. Monitor enrollment goals and modify recruitment strategies as necessary
- b. Informed Consent/Assent
 - i. Ensure the protection of human subjects (e.g., Declaration of Helsinki)
 - ii. Explain study to subject (e.g., purpose, duration, risks/benefits)
 - iii. Assess subject understanding of study requirements
 - iv. Obtain required signatures
 - v. Provide subject/legal guardian a copy of informed consent form
 - vi. Document obtaining informed consent in source document
 - vii. Obtain informed consent from vulnerable subject populations
- c. Scheduling/Screening
 - i. Screen potential subjects (e.g., to obtain medical history, medications/medical/surgical history)
 - ii. Schedule subjects
 - 1. Determine length and timing of visits
 - 2. Coordinate subject visits with support services (e.g., subject, physician, ancillary staff, coordinator)
 - 3. Determine payor responsibility for designated study visit
 - iii. Send reminders for scheduled visits to subjects
- d. Study Conduct
 - i. Perform subject interview and assessments at study visits
 - ii. Monitor study team compliance with protocol, GCP, SOPs and regulations
 - iii. Assure subject safety during trial participation
 - iv. Coordinate/perform study-related procedures (e.g., phlebotomy, vital signs, ECG)

4. Documentation and Administration (20 questions)

- a. Case Report Forms
 - i. Review inclusion/exclusion criteria
 - 1. Make required calculations (e.g., convert units of measurement)
 - 2. Document concomitant medications
 - 3. Document medical history
 - ii. Enter data for specific visit on CRF
 - iii. Enter data using electronic data capture systems (e.g., eCRF, PDAs)
 - iv. Verify study data for accuracy
 - v. Transmit data (e.g., fax, express mail, EDC) as required by Sponsor/CRO
 - vi. Complete and return Sponsor/CRO queries
- b. Source Documentation
 - i. Develop checklist for source documentation of study events

- ii. Incorporate applicable historical documents (e.g., surgical reports, pathology reports, medical history)
- iii. Obtain and record ancillary services reports (e.g., x-ray, pathology, ECG, laboratory)
- iv. Maintain progress notes
- v. Update subject screening/enrollment log
- vi. Document written, electronic, and verbal communication with study contacts (e.g., subject, Sponsor/CRO, IRB/IEC, laboratory)
- vii. Document protocol deviations/violations
- viii. Maintain communication with IRB/IEC regarding

- 1. Continuing review
- 2. Serious adverse events
- 3. Safety reports
- 4. Protocol amendments
- 5. Protocol deviations/violations
- 6. Informed consent modifications
- 7. Final report

c. Financial/Budgetary Issues

- i. Assist in the preparation of the budget for study-related costs and associated services
- ii. Reconcile outstanding financial consideration for study-related services and payments

125 Total Questions

Exam Preparation

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

- ICH Guidelines (E2A, E6, E8)
- Declaration of Helsinki* (latest version)
- *A Guide to Clinical Trials*, Bert Spilker (1991), ISBN: 0-88167-761-1 (recommended)
 - Study designs
 - Pharmacokinetic principles

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.

ACRP also offers optional certification exam preparation materials:

- ACRP Prep Materials: <http://www.acrpnet.org/prepareforyourexam>

Sample Exam Questions

The following sample questions show the type of questions that will appear on the CRA Exam.

1. Which of the following does not require IRB/IEC approval?
 - a. Investigator's drug brochure
 - b. Addendum to an approved informed consent
 - c. Advertisement for subject recruitment
 - d. Amendment to an approved study protocol
2. Which of the following would be considered a Serious Adverse Event?
 - a. Migraine headache
 - b. Stroke with hemiplegia
 - c. Maculopapular rash treated with cortisone cream
 - d. 12-hour observation in an emergency room for a bee sting
3. Which of the following documents must be evaluated for approval by the IRB/IEC? 1. Investigator's Brochure; 2. Protocol; 3. Laboratory certification; 4. Informed consent form
 - a. 1 and 3 only
 - b. 2 and 4 only
 - c. 1, 2 and 3 only
 - d. 1, 3 and 4 only
4. Which of the following is true regarding the study protocol? It must:
 - a. Contain information on the bio availability of the investigational product
 - b. List the name and address of the responsible ethics committee(s)
 - c. Include a description of the statistical methods to be employed
 - d. Define the quality assurance auditing procedures

Answers: 1, A; 2, B; 3, B; 4, C

APPLICATION, TESTING PROCEDURES

ACRP offers the Clinical Research Coordinator (CRC) Certification exam to qualified individuals. This exam was developed in response to overwhelming interest and the need for certification as expressed by CRCs and their managers.

Application Instructions

Please read the following information carefully.

Before completing the application form, please verify that you are applying for the correct exam. The ACRP website contains online exam applications* and a link to printable applications for those that need to pay with a check. If you choose to do the online version of the application, please follow the online application instructions and submit electronically. If completing the printable application, make sure the application is received by ACRP by the deadline to avoid the late fee.

A detailed résumé or C.V., showing detailed job functions, specific employment dates (do not include list of studies), and a job description must be included with the application.

If a candidate submits their application based on the substitution of one year of CRC work experience, then the following information needs to be added to their CV (See Appendix 1 for Sample CV) and a certificate of completion must also be submitted:

- Clinical Research Education (only required if claiming completion in lieu of 1 year of CRA experience)
- Name of School
- Program Title
- Name of Organization that Accredits the Education Institute Providing this Program
- Dates Attended (From-To)

Notices of confirmation of receipt of exam application and exam eligibility will be e-mailed. Please take any necessary steps to prevent filtering of ACRP/APPI emails.

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, understand, and agree to abide by the ACRP/APPI Unified Code of Ethics.

Applications will be verified for accuracy and completeness.

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

Application Deadlines, Exam Dates

In order to apply for an exam, a candidate must submit either the online or printable exam application found on <http://www.acrpnnet.org> along with a copy of a detailed résumé or C.V., that shows job functions and specific employment dates, a job description and the appropriate fees by the application receipt deadline for that exam. The exam dates and application **receipt** deadlines (NOT postmark deadline) are as follows:

Exam Dates	Exam Application Deadlines	Applications Accepted with Late Fee
September 16-25, 2010	August 3, 2010	August 4-16, 2010
March 3-12, 2011	January 23, 2011	January 24-February 6, 2011

Late and/or incomplete applications will not be accepted and will not be returned.

A nonrefundable \$110 application fee is included in the exam fee. It is the candidate's responsibility to assure that the application is complete and received by ACRP by the filing deadline.

If your application was submitted online, an email confirmation is automatically sent. This verification also confirms that your application was received by ACRP and should be kept with your records. PLEASE NOTE: This confirmation does not confer eligibility. A separate notification will be sent regarding an eligibility decision.

For those submitting the printable application, for the candidate's protection, it is highly recommended that the application be mailed to ACRP via certified mail, express parcel service, or a trackable 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.

If submitting a printable application, an email confirmation will be sent to you. This verification confirms that your application was received by ACRP and should be kept with your records. PLEASE NOTE: This confirmation does not confer eligibility. A separate notification will be sent regarding an eligibility decision.

Application Confirmation and Acceptance

An email confirmation is automatically sent once payment is processed. This verification also confirms that your application was received by ACRP, acts as a receipt and should be kept with your records. PLEASE NOTE: This confirmation does not confer eligibility. A separate notification will be sent regarding an eligibility decision.

The application review includes completeness of the application package and whether or not the candidate meets the eligibility criteria for the exam. Eligibility notification will be provided two to three weeks after receipt of the application once processing begins.

Candidates who are determined to be eligible will receive a confirmation notice including a Prometric Testing ID number. The candidate will use this number to log onto the Prometric website to select an exam date, site and time slot. Directions are also available, which will enable the candidate to locate accommodations nearby.

Scheduling Site Selection, Exam Date and Time Slot

ACRP now offers a 10-day testing window in both March and September. Once a candidate receives notice that they are eligible, they must visit the Prometric website at <http://www.prometric.com/acrp> to schedule their site selection, exam date and time slot. ACRP will include information required to register on emailed eligibility notices. Your ACRP record number will serve as your Prometric Testing ID# when you go to the Prometric website to schedule.

Ineligibility Decision Appeals Process

ACRP makes every attempt to make fair and accurate eligibility decisions based on the information provided by the applicants. Should an ineligibility decision be made, the applicant will be notified by email with an explanation of the deficiency identified. The applicant may contest the ineligibility decision by contacting the Director of Credentialing and Certification to discuss in detail the reason/s for the decision. In many cases, providing additional information or clarifying submitted documentation may result in an eligibility decision. If this is not the case and the applicant insists on their eligibility to take the exam, their

application and supporting documents will be reviewed by the Chair of the appropriate Exam Committee. The Exam Committee chair decision on eligibility is final.

Fees

Only applications received with full payment and all required documentation will be processed. If applying online for the exam and you are planning on joining/re-joining ACRP, you should join first before applying for the exam to activate the member price on the exam application. Country of residence determines membership rate. To view membership rates visit the membership section of the website. **The membership fee is nonrefundable. All exam fees include a non-refundable \$110 application fee regardless of eligibility status or cancellation.** The late fee is non-refundable also.

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

CRC Exam Regular Fee - \$620	CRC Exam Member Fee - \$440
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Fees for the CRC exam are noted above. The regular fee pertains to those who are **not** current members of ACRP. The member fee pertains to ACRP members only.

To calculate the exam fee with membership prices included, use the fee calculator located at: <http://www.acrpnnet.org/crccertification>.

Rescheduling Exam or Cancellations

If a candidate has scheduled their exam site with Prometric and needs to either reschedule or cancel their appointment, the following information applies:

Time Frame	Who to Contact	How to Contact
Exam Rescheduling or Cancellation Greater than 29 Days Prior to Exam	ACRP (in writing)	certification@acrpnnet.org
Exam Rescheduling or Cancellation 16-29 Days Prior to Exam	Contact Prometric first to pay \$25 and then notify ACRP (in writing)	(800) 853-6769 certification@acrpnnet.org
Exam Rescheduling or Cancellation 5-15 Days Prior to Exam	Contact Prometric first to pay \$50 and then notify ACRP (in writing)	(800) 853-6769 certification@acrpnnet.org
Exam Cancellation Less than 5 Days Prior to Scheduled Exam	ACRP (no refunds permitted)	certification@acrpnnet.org

If a candidate has not yet scheduled their exam site with Prometric and needs to either reschedule or cancel their exam, then the following information applies:

Exam Rescheduling or Cancellation 15 Days or More Prior to Exam Cycle	Contact ACRP (in writing)	certification@acrpnet.org
Exam Rescheduling or Cancellation Less than 15 Days Prior to Exam Cycle	Contact ACRP (in writing; no refunds permitted)	certification@acrpnet.org

Only the candidate may request a cancellation, regardless of whether the exam fee is paid by the candidate or another party. All cancellation requests must be made in writing and received at least 15 days prior to the exam.

Refunds

Any changes to information submitted in the original application must be requested in writing to certification@acrpnet.org. Please include name, the exam you signed up to take and the reason for canceling.

If a candidate must cancel an application, the total fee, **less** the \$110 nonrefundable application fee, the nonrefundable membership fee, and the late fee if applicable, may be refunded, provided that the request for cancellation is received at least 15 calendar days prior to the exam. Cancellation requests received after that time will not be refunded. Fees are **nontransferable** to future exams. No refunds are available to candidates who do not show up for the exam.

Candidates who do not meet the eligibility requirements for the exam, or who are ineligible due to an incomplete application, will receive a refund, less the \$110 nonrefundable application fee and, if applicable, the nonrefundable membership fee and the late fee.

The refund will be sent to the party who initially paid for the exam. If payment was made by a credit card then that card will receive the credit. If the payment was made by check, ACRP will mail a refund check to the original payer.

Test Center Selection

Visit <http://www.prometric.com/acrp> to view available test centers.

If a candidate wishes to change their site selection, they must do so by 5 calendar days prior to their appointment using the Reschedule/Cancel option on the Prometric website or by contacting Prometric's automated voice response system at 888-226-8804 (in North America) or by contacting Prometric's Regional Administration Center (outside North America). There is no charge for changing an appointment within the same testing window if the change is made **more than 30** days prior to your appointment. **However, there is a \$25 charge for any changes made 15-29 days prior and \$50 for 14 days or less. This fee should be paid directly to Prometric.**

For help with selecting your site, view this document: http://www.acrpnet.org/PDF/Exam_Sites.pdf.

Services for People with Special Needs

ACRP is committed to ensuring that no individual with special needs or a disability is deprived of the opportunity to take an exam solely by reason of that disability. ACRP will provide reasonable accommodations for candidates with disabilities. 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 special accommodations and arrangements.

To indicate a special need, check the appropriate box on the application. See Appendix 2 of this guide to obtain the Special Accommodations form. Also, a link to the special accommodations form is available on both the online and printable applications. Complete and submit with your application.

Exam Schedule and Admission Details

Identification: You will be required to present two (2) forms of identification at the test center. Your primary form of identification must be a current government-issued picture ID that includes your signature (e.g. driver's license or passport). A second form of ID must also be presented and must include your signature (e.g. credit card or marriage license).

Your name as it appears on your exam application must match the name on your primary and secondary forms of identification. If the name listed on your application is not correct, contact the ACRP office immediately (before your test appointment) at certification@acrpnet.org.

You will not be admitted to the exam without proper identification. If you arrive at the test center without proper ID, your appointment will be forfeited and you 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 goes to through the test center selection. It is the candidate's responsibility to arrive on time. If the candidate is late by 15 minutes or more, the site has the authority to turn him/her 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 site availability. 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.

Between check-in time, pre-exam procedures (computer tutorial), exam and post-exam evaluation, be prepared to stay at the exam site 3 ½ to 4 hours.

- **Length of the Exam:** All certification exams have a time limit of three hours from the time the official exam is started.
- **Supplies Needed:** An online calculator will be available at the test center and whiteboard will be provided for comments. Study aids are not permitted. Language 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.)

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. Lastly, each exam will be delivered via individual video-monitored testing carrels both for better privacy while the candidate is taking the exam and better prevention of 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>.

Any individual who removes or attempts to remove exam material from the testing site will be prosecuted.

Exam Scoring

Prometric scores all exams. 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 1 to 99. The passing **scaled** score is 70 for each exam. The passing score reflects the minimum amount of knowledge a committee of experts has determined to be appropriate for certification, according to accepted testing development guidelines.

A criterion-referenced, or standard-setting procedure and expert judgment are used to identify the passing point. A candidate's ability to pass the exam depends on the amount of knowledge he or she displays, 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 base passing raw score. If the exam is a bit easier, then the passing raw score will be slightly higher. Equating helps ensure that the

passing scaled score represents the same level of knowledge, regardless of which version of the exam a candidate takes.

Exam Results

Computer-based testing provides participants with preliminary results immediately, with confirmation of results following within 30 days. Candidates that pass the exam will also be sent a certificate and certification maintenance 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 ACRP certification registry unless they do not opt-in for inclusion. 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 to ACRP at certification@acrpnet.org. If requesting by e-mail, please include credit card information. If not paying by credit card, mail request and payment to ACRP.

Revocation of Certification

ACRP may revoke certification, or take other disciplinary 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 action, in the event that an individual is in violation of the ACRP code of ethics or has regulatory or professional restrictions placed on his or her clinical research practice or professional license. If a certificant is notified of revocation, he/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.

FREQUENTLY ASKED QUESTIONS

How will I know if my exam application was received?

An email confirmation is sent once payment is processed. The confirmation is notice that your application was received and acts a receipt. If submitting a paper application, consider submitting your application via certified mail or express parcel service. These services provide receipts. If your application is faxed, be sure to keep the fax confirmation with your records.

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

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

What should I bring to the test center?

Bring appropriate identification. Online calculators will be provided.

What happens if I need to cancel the exam?

If a candidate has schedule their appointment with Prometric, then:

1. Contact Prometric to cancel the appointment
2. Pay the appropriate cancellation fee to Prometric
3. Notify ACRP in writing at certification@acrpnet.org once appointment is cancelled

If the candidate has not yet scheduled an appointment with Prometric, then the candidate should notify ACRP in writing at certification@acrpnet.org.

If you cancel at least 15 days prior to the exam, you will receive the exam fee, less the \$110 nonrefundable application fee and the nonrefundable membership fee. Late fees are non-refundable as well. No refunds are available after less than 15 days prior to the exam. ACRP does not allow transfers to another exam window.

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 registration receipt deadline?

All registrations must arrive at ACRP (not postmarked) by the application receipt deadline. Faxed applications will be accepted. If you do 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?

ACRP provides resources to purchase to help individuals prepare for the exam.

You may purchase an optional Online Certification Exam Preparation Package which includes three (3) sections: a Certification Exam Preparation Guide, a Helpful Hints document, and a 50-question Self-Assessment Test. If you're comfortable with independent study, this comprehensive package will give you the guidance you need to make the most of your study time.

What is ACRP's Maintenance of Certification process?

ACRP requires periodic certification maintenance to ensure that individuals who hold a CCRA[®], CCRC[®], or CCTI[®] credential maintain their ongoing commitment to professional development in their selected area of practice. Through the maintenance requirements, certificants demonstrate expansion and reinforcement of their knowledge of current practice.

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

CCRA[®]s, CCRC[®]s, and CCTI[®]s must maintain every two (2) years from the time of original certification. The two year maintenance cycle is based on the frequency of changes in the clinical research field. Maintenance requires the completion of 24 documented continuing education contact hours. A minimum of 12 of the 24 hours completed **MUST** be in clinical research continuing education topics. Effective

January 1, 2010 Certification Maintenance 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 (one time only)
- Authoring/presenting a ½ day workshop – 6 points per workshop – 12 points maximum (one time only)
- Authoring/presenting a 1 day workshop – 12 points per workshop – 12 points maximum (one time only)

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

A minimum of 8 continuing education contact hours must be in clinical research topics.

CPI®s must maintain every two (2) years. Maintenance requires the completion of 24 documented points, 12 being in Continuing Involvement and the other 12 in Continuing Education. CPIs must also submit a copy of their current medical license. There is a table in the CPI Maintenance of Certification Guide that outlines the points needed to fulfill the two arms of the maintenance program. There are maximum points allowed for each activity.

What records of continuing education and/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 audit. ACRP will request these records if needed. All continuing education activities submitted for certification maintenance are subject to review and approval. ACRP reserves the right to request additional information and to verify any documentation. 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 Certification Maintenance Guide explains that acceptable courses for earning accredited continuing education contact hours include:

- 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 offering continuing education contact hours. (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 submit 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 and successfully pass the exam.

NON-DISCRIMINATION POLICY

It is ACRP/APPI'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

ACRP 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 ACRP registry on the ACRP website. Requests for written verification may be requested by contacting the ACRP office and will require a signed release from the certificant.

CERTIFICATION MARK USE

ACRP grants limited permission to individuals who have met all of the certification eligibility criteria, passed the exam, and received notification of certification from ACRP to use the CCRA®, CCRC® and/or CCTI® designations that have been granted to them.

Use of the CCRA®, CCRC® and/or CCTI® 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 may result in disciplinary action.

The CCRA®, CCRC® and/or CCTI® designations are trademarked property of the ACRP and use of the designations is subject to approval by ACRP.

DISCIPLINE AND COMPLAINTS POLICY

ACRP enforces the ACRP/APPI Uniform Code of Ethics and Professional Conduct for all CRA, CRC and CTI certificants and individuals in the process of obtaining CRA, CRC or CTI 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. Adverse disciplinary decisions made by ACRP (or its sub-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 the 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 CRC 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 Coordinator 12/1/2005 to present
JKL Hospital
Research Department

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 Coordinator 6/22/2004 to 11/30/2005
University of XYZ Medical Center
Division of Cardiovascular Diseases

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.

APPENDIX 2 – SPECIAL ACCOMMODATIONS FORM

Please have this form completed by an appropriate, licensed health professional to ensure that Prometric is able to provide the required 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 exam application, or fax to 703-254-8102, attention of Certification Department, by August 3, 2010.

Professional Documentation:

I have known (Exam Candidate) _____ since (Date) _____ in my capacity as (Professional Title) _____.

The candidate discussed with me the nature of the examination being administered. It is my opinion that because of this candidate's disability described below, he/she should be accommodated by providing the special arrangements listed below.

Disability _____

Please check all that apply:

Separate Testing Room ZOOMTEXT Extra Breaks

Extended Testing Time, select the extra time needed ½ hour 1 ½ hour 3 hours

Other (describe in detail below)

Accommodation is being requested for the CRA CRC CPI exam in (city, state) _____

Print Name _____

Print Address _____

Phone _____

Signature _____

Date _____