ICH CRC Certification Guide – September 2009

General Information

Benefits *of Certification*

A survey of 357 experienced CCRCs cited personal satisfaction, increased knowledge, and professional recognition as the primary reasons for achieving certification.
In addition:

- 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.
- The largest investigator online databases include a request for the study coordinator's certificate number.
- Certification assists the public, healthcare professionals, and the industry itself by identifying standards for professional practice.

Industry Recognition

Based on a survey of CRCs, those surveyed believed that enhanced professional standing, increased company marketability (for CROs), personal satisfaction, and enhanced recognition by peers and supervisors were the primary anticipated advantages for becoming certified.

About the Exam

The Academy offers the Clinical Research Coordinator Certification Examination (CRC) to qualified individuals. Accreditation as a CRC signifies that a clinical research professional possesses knowledge about the conduct of clinical trials. Certification assists the public, other health care professionals and the industry by identifying standards for professional practice.

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) and ICH Guidelines. CRCs and other professionals referred to as research nurses, trial nurses, site coordinators, etc., perform tasks such as:

- Verifying study feasibility
- Facilitating formal approval
- Planning trial execution
- Assisting in subject recruitment
- Coordinating study procedures
- Collecting accurate and verifiable data
- Safeguarding GCP, protocol and investigational product compliance

- Communicating with the sponsor and regulatory authorities (including audits & inspections)
- Coordinating study close out

To qualify to take the CRC Exam, a candidate must, at a minimum, coordinate study procedures, collect data and communicate with the sponsor and regulatory authorities.

The CRC Exam is a measure of the candidate's general skills and knowledge of the information needed for CRCs to perform effectively. Certification is granted in recognition of the candidate's documented education and working experience as a CRC, and successful completion of this written exam. By granting the title of Certified Clinical Research Coordinator (CRC), The Academy is formally recognising the professional CRC who has provided evidence that he or she meets those professional standards.

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 two combinations of education and working experience as a CRC. For the purpose of meeting the working experience requirement, a minimum of 2 years full time or 4 years part time must be completed prior to the exam date. A detailed résumé or C.V. and a job description is 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 C.V. 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 C.V. (See chart for educational requirements.)

Option	Education	Working Experience as a CRC
1	University degree or Paramedical Qualification (e.g., nurse, pharmacy assistant, medical documentation specialist, etc.)	2 years full-time or 4 years part-time
2	Other education	4 years full-time or 8 years part-time

(NOTE: A minimum of 40 hours per week qualifies as full-time employment, and a minimum of 20 hours per week qualifies as part-time employment.)

Those candidates who meet eligibility requirements and pass the exam will be certified as having met The Academy standards for becoming a CRC, as adopted by The Academy. 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. The Academy has the right to verify qualifications. A detailed résumé or C.V. must also be included with the application. This must include a description of your roles as a CRC and specific employment dates. The C.V. that is provided to the sponsor is not sufficient because it does not show job function performance.

Language

The CRC Certification Exam in ICH regions is provided in the English language.

Please note: Exam candidates in ICH regions 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 centre, invalidation of the exam score, and possible legal action

CRC Exam Content

The Academy's CRC Certification Exam Committee develops the CRC Exam in ICH regions. The Committee regularly evaluates and improves the existing exam questions, and adds new questions to expand the ICH region 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 ICH 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. **Evaluates protocol consistency and currency, and examines feasibility of study in practice (25 items)**
    a. Ensures that personnel and infrastructure requirements can be met
    b. Prepares for pre study visit (site selection) and site initiation
    c. Facilitates compliance of research team qualifications with GCP and regulatory needs and collects key documents (e.g. Curriculum Vitae (CV))
    d. Assesses the protocol for site operational feasibility and advises on the site budgetary requirements
    e. Verifies that the informed consent form and patient information complies with ICH-GCP and any local requirements
    f. Advises on patient population (suitability, availability) and
    g. Facilitates effective communications both site-based and with key stakeholders
2. **Facilitates or verifies formal approvals according to local and regional requirements (Investigational Review Board (IRB), Independent Ethics Committee (IEC), Scientific Committee, hospital board etc.) (10 items)**
3. **Develops the plan for study implementation (0 items, at the time of this printing)**
    a. Facilitates the selection of the investigational staff
    b. Assures that appropriate training is given to investigational staff
    c. Manages and motivates the investigational staff and other disciplines involved
    d. Assures a quality-driven approach, compliant with ICH-GCP and other regulations

e. Generally attends and participates in the Investigator meeting
f. Develops and uses formal planning tools (and a written project management plan)
g. Assures that there are valid operational and administrative tools and processes, including key document tracking and validation of electronic instruments such as computer programs, recording or measurement devices
h. Checks and advises on viability and consistency between Standard Operation Procedures (SOP) and the study protocol
i. Checks on congruence of data collection tools (e.g. Case Report Form (CRF), electronic data capture) with protocol and other study documentation
j. Works to a (written) project management plan
k. Checks availability & storage of investigational product and supplies
l. Organises receipt and return (where indicated) of study materials and other supplies
m. Assures collaborative working relationship with Sponsor

4. **Assists in recruiting trial subjects (10 items)**
    a. Evaluates appropriate recruitment strategies
    b. Develops and implements the recruitment strategies
    c. Assures compliance with data protection requirements
    d. Verifies the eligibility of potential trial subjects
    e. Verifies subject's understanding of the written patient information
    f. Assures that the informed consent process is in accordance with ICH-GCP or other regulatory authorities.
5. **Co-ordinates the performance of study-related procedures (35 items)**
    a. Schedules appointments / study visits
    b. Verifies that the inclusion and exclusion criteria are met
    c. May assist in performing study related screening procedures
    d. Assures the proper collection, processing, storage and shipping of samples
    e. Assures compliance with health and safety regulations
    f. Establishes and maintains professional relationship with subject(s)
    g. Assures compliance with study specific requirements, such as randomisation, blinding procedures and drug regimen
    h. Provides subject with appropriate written and verbal background information
    i. Monitors early warning indicators for Adverse Events (AE), Serious Adverse Events (SAE), Adverse Drug Reaction (ADR), Unexpected Adverse Device Reactions (UADR)
    j. Responds quickly and appropriately to Adverse Events (AE), Serious Adverse Events (SAE), Adverse Drug Reaction (ADR), Unexpected Adverse Device Reactions (UADR)
    k. Assists in the appropriate documentation and reporting of AE, SAE, ADR, UADR
    l. Operates appropriate procedures for dealing with and reporting accidents in the work place

6. **Collects accurate and verifiable data (15 items)**
    a. Completes data collection tools and/or other study documentation
    b. Assures access to source data under appropriate rules (e.g. site, national laws on ownership and access)
    c. Maintains confidentiality of records and limits access accordingly
    d. Develops, completes and/or collects source documentation
    e. Files and archives study documentation
    f. Assures query resolution e.g. with CRA
7. **Assures ICH-GCP, protocol and investigational product compliance and implementation of corrective actions (10 items)**
    a. Protects subject safety and welfare
    b. Assures adherence to study specific requirements
    c. Implements and documents corrective actions
8. **Communicates with the sponsor (10 items)**
    a. Facilitates monitoring visits and activities
    b. Prepares the study site for audits & inspections
    c. Responds to or facilitates response to audit/inspection findings
9. **Co-ordinates the study close-out (10 items)**
    a. Ensures timely completion of data collection tools
    b. Assures complete investigational product accountability
    c. Assures follow-up care for study subjects
    d. Assures close-out reporting to the IRB/IEC and/or other parties involved
    e. Provides the investigator with the necessary assistance and inputs to the final report.

125 Total Questions

CRC Exam Preparation

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

- ICH Guidelines (E2, E6, E8)
- Declaration of Helsinki (latest version)
- *A Guide to Clinical Drug Research: 2nd Edition*, A. Cohen & J. Posner (2000), ISBN: 0-7923-6172-5 (recommended)
    - Study designs
    - Pharmacokinetic principles

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

1. Declaration of Helsinki* (latest version on the Web site) http://www.wma.net/e/policy/b3.htm
2. ICH Guidelines (e.g. E2—Clinical Safety, E6—GCP) 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.

An online European/ICH CRC practice exam is also available from the Online European/ICH CRA Practice Exam Web site at http://www.acrpnet.org/MainMenuCategory/Certification/ExamPreparation/ICHEUPracticeExams.aspx

CRC Sample Exam Questions

The following samples show the type of questions that will appear on the CRC 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

Contact Information

All correspondence and requests concerning CRC exams or Certification Maintenance should be directed to:

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Alexandria, VA 22314-1560
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These requests may include: change of address, change of test center location, admission ticket was not received, duplicate score report, hand scoring of the answer sheet and cancellation request. All fees must accompany the request.

Non-Discrimination Policy

The Academy does not discriminate on the basis of age, gender, race, disability, marital status, sexual preference, religion, or national origin.