ACADEMY
OF CLINICAL RESEARCH PROFESSIONALS

# Certified Clinical Research Coordinator (CCRC®) Examination Detailed Content Outline

*(Effective October 2019)*

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

## Introduction

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

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

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## Using the CCRC Detailed Content Outline (DCO)

The CCRC DCO was constructed from the results of the most recent (2019) Job Analysis Study. The results of the study provided the framework for the knowledge and tasks important to the role of a CCRC and therefore the content of the CCRC Exam. To be certified, a CRC is expected to have proficiency in the six (6) main content areas of clinical research, displayed in the chart below. The percent of questions dedicated to each content area are provided.

| | Content Areas | Percentage of Items on Exam |
|---|---|---|
| I. | Scientific Concepts and Research Design | 8% |
| II. | Ethical and Participant Safety Considerations | 20% |
| III. | Product Development and Regulation | 14% |
| IV. | Clinical Trial Operations (GCPs) | 23% |
| V. | Study and Site Management | 22% |
| VI. | Data Management and Informatics | 13% |
| | **Total** | **100%** |

Certified Clinical Research Coordinators (CCRCs) are expected to have general knowledge of:
- laboratory terminology, tests, and procedures
- basic math, including adding, subtracting, multiplying, dividing, and calculating percentages

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

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

| **Domain I – Scientific Concepts and Research Design – 8% of exam** | |
|---|---|
| **Knowledge Statements** | **Tasks** |
| Elements of a protocol | • Identify and/or explain study design<br>• Identify and/or explain study objective(s)<br>• Identify and/or explain study endpoints |
| Elements of an Investigational Brochure (IB) and/or investigational device use (instructions for use, user manual) | |
| Elements of and rationale for subject eligibility requirements | |
| Rationale for complying with a protocol | |
| Statistical principles related to study design (e.g., sample size, screen fail rate) | |
| Study design characteristics (e.g., double-blind, crossover, randomized) | |
| Study objective(s) | |
| Study endpoints/outcomes | |
| Rationale for using supplemental/ rescue/comparator product in study design | |
| Treatment assignments (e.g., randomization, open label, registries) | |
| **Domain II – Ethical and Participant Safety Considerations – 20% of exam** | |
| **Knowledge Statements** | **Tasks** |
| Adverse events classification, documentation and reporting | • Identify the safety and expected/unexpected therapeutic effects of the investigational product using various study documents including the protocol and IB<br>• Develop and/or follow a recruitment strategy<br>• Develop and/or review informed consent form<br>• Conduct prescreening activities with potential study subjects<br>• Screen trial subjects |
| Blinding/unblinding procedures | |
| Components of subject eligibility requirements | |
| Confidentiality and privacy requirements | |
| Elements of the IB related to identifying risks and benefits | |
| Elements of the informed consent form | |
| Informed consent process requirements (e.g., paper, eConsent, assent) | |

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| Protection of human subjects<br>Protocol deviation/violation identification, documentation, and reporting processes<br>Subject recruitment and retention plan/strategies (e.g., social media, digital, print)<br>Safety monitoring and elements of pharmacovigilance and/or product/device vigilance (e.g., CIOMS, IDMC/DSMB, safety databases)<br>Subject discontinuation criteria/procedures<br>Subject safety processes<br>Vulnerable subject populations<br>Conflicts of interest in clinical research<br>Principal investigator ethical responsibilities | • Comply with subject privacy regulations<br>• Participate in the informed consent process(es)<br>• Ensure adequate consent and documentation of the informed consent process<br>• Develop and/or implement education plan and/or tools for study-related activities for subjects<br>• Ensure and document medical care for study subjects, as applicable<br>• Ensure the assessment, management, and review of subject laboratory values, test results, and alerts<br>• Differentiate the types of adverse events that occur (e.g., serious vs non-serious, expected vs unexpected)<br>• Implement plan of action for management of adverse event(s) (e.g., stop investigational product, retest, treat subject)<br>• Maintain follow-up to determine resolution of adverse event(s)<br>• Ensure appropriate reporting and documentation of adverse event(s)<br>• Ensure timely review of safety data<br>• Ensure assessment and documentation of subject safety during study participation<br>• Ensure the management of safety risks at the site (e.g., clinical holds, product recalls)<br>• Coordinate unblinding procedures as applicable<br>• Document reasons for subject discontinuation (e.g., causes, contact efforts)<br>• Identify and/or address potential ethical issues involved with study conduct (as referenced in ICH GCP and applicable local regulations)<br>• Identify and report suspected fraud and misconduct<br>• Inform study subjects of trial results, in accordance with regulatory requirements |

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| Domain III – Product Development and Regulation – 14% of exam | |
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| **Knowledge Statements** | **Tasks** |
| Audit and inspection processes (preparation, participation, documentation, and follow-up)<br>Clinical development process (e.g., preclinical, clinical trial phases, device class)<br>Clinical trial registries and requirements<br>Elements of fraud and misconduct<br>IRB/IEC and other regulatory body reporting requirements<br>IRB/IEC role, composition, and purpose<br>Protocol and protocol amendment submission and approval processes<br>Safety reporting requirements<br>Significant milestones in the evaluation of efficacy and safety (e.g., interim analysis result, DSMB review)<br>Management of hazardous goods (e.g., International Air Transport Association (IATA)) | • Comply with IRB/IEC requirements<br>• Identify the role and proper composition of IRB/IECs<br>• Prepare and/or submit documents for review/approval by IRB/IEC, sponsor, and/or other regulatory authority<br>• Ensure IRB/IEC review/written approval of study and study documents<br>• Inform the sponsor and/or IRB/IEC of any protocol deviations and document as appropriate<br>• Prepare and/or submit study summary and/or close-out letter for IRB/IEC<br>• Ensure compliance with study requirements and regulations<br>• Prepare for and/or participate in study site audits and inspections<br>• Facilitate response to post-audit/inspection findings<br>• Follow standards for handling hazardous goods (e.g., International Air Transport Association (IATA)) |
| **Domain IV – Clinical Trial Operations (GCP) – 23% of exam** | |
| **Knowledge Statements** | **Tasks** |
| 1. delegation of responsibilities and duties<br>2. elements of effective corrective and preventive action (CAPA) process(es) and plan(s)<br>3. elements of and rationale for monitoring plan(s)<br>4. indemnification/insurance requirements<br>5. monitoring activities (frequency of visits, data review, and follow-up)<br>6. pre-study/site selection criteria and visit activities<br>7. principal investigator oversight responsibilities<br>8. principles of risk-based monitoring<br>9. project feasibility considerations<br>10. roles of various clinical trial entities (e.g., | • Evaluate study for feasibility (site determining ability to successfully conduct the study)<br>• Coordinate protocol and/or protocol amendments through appropriate approval processes (e.g., IRB/IEC, sponsor, regulatory authority)<br>• Ensure and maintain consistency between the site standard operating procedures (SOPs) and the study requirements<br>• Confirm that investigational staff is qualified<br>• Develop or participate in protocol training, and document<br>• Identify and minimize potential risks to |

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| CROs, sponsors, regulatory authority)<br>11. site close-out activities<br>12. site initiation activities<br>13. staff qualifications (site and monitor)<br>14. staff training requirements<br>15. study close-out activities | subject safety<br>• Identify issues requiring protocol amendments<br>• Implement protocol amendments<br>• Review the Investigator Brochure<br>• Schedule, coordinate, and/or participate in pre-study and site initiation visits<br>• Develop trial management tools (e.g., subject study calendar, source documents, retention material)<br>• Prepare for, facilitate, and/or participate in interim monitoring activities visit(s) (including onsite, remote, and risk-based)<br>• Ensure investigator/site protocol compliance<br>• Follow up on and communicate regarding monitoring/site visit findings<br>• Create, document, and/or implement corrective and preventive action (CAPA) plans<br>• Escalate significant issues/concerns as appropriate<br>• Prepare for, facilitate, and/or participate in close-out monitoring visit<br>• Identify the Essential Documents required for study conduct |
| **Domain V – Study and Site Management – 22% of exam** | |
| **Knowledge Statements** | **Tasks** |
| Communication documentation requirements between all study entities<br>Contract/budget negotiations and approval process<br>Content of a study budget and/or invoicing<br>Equipment and supplies use and maintenance<br>Investigational product accountability and documentation requirements<br>Study staff training procedures and documentation requirements<br>Investigational product characteristics (e.g., mechanism of action, stability, product attributes)<br>Investigational product labeling requirements | • Implement a study plan as applicable<br>• Select and manage local vendors and/or ancillary services, including obtaining/verifying credentials (e.g., certification/licensure)<br>• Participate in budget development<br>• Facilitate site budget/contract approval process<br>• Prepare for, coordinate, and/or participate in study start-up activities<br>• Plan, conduct and/or participate in training of the investigational staff<br>• Schedule subjects |

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| Investigational product packaging<br>Investigational product shipment<br>Investigational product storage<br>Non-compliance management<br>Project timelines (e.g., data lock, enrollment period, recruitment/retention)<br>Purpose of and process(es) for protocol compliance<br>Sample collection, processing, shipment, and storage requirements<br>Subject compliance assessment<br>Subject responsibilities for study participation<br>Subject visit activities<br>Vendor management | • Conduct subject visits<br>• Instruct subjects on proper use of investigational product<br>• Assess subject compliance<br>• Reevaluate the recruitment strategy as needed<br>• Maintain study-related logs (e.g., site signature log, screening log)<br>• Manage study supplies (e.g., lab kits, case report forms)<br>• Perform and/or verify equipment calibration and maintenance<br>• Ensure proper collection, processing, and shipment of specimens (e.g., centrifuge, preparation of slides, freezing, refrigeration)<br>• Ensure appropriate staff, facility, and equipment availability throughout the study<br>• Ensure monitoring activities are conducted according to plan<br>• Reconcile payments per contract (e.g., stipend payments)<br>• Maintain randomization procedures of investigational product<br>• Maintain blinding and unblinding procedures of investigational product<br>• Ensure proper inventory (including expiration), storage, handling, and disposition of investigational product and related supplies<br>• Reconcile and maintain accountability of investigational product and related supplies<br>• Manage investigational product recall<br>• Identify and escalate product complaints or discrepancies |
| **Domain VI – Data Management and Informatics – 13% of exam** | |
| **Knowledge Statements** | **Tasks** |
| Data management activities<br>Data privacy principles<br>Elements and purposes of data collection tools (e.g., eCRF, EDC, IWRS blinding) | • Develop source document templates<br>• Evaluate data collection tools (e.g., case report form (e/CRF), electronic data capture |

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| Elements of a clinical study report | (EDC)) for consistency with protocol<br>• Review and submit completed eCRF/CRF<br>• Maintain Essential Documents required for study conduct<br>• Collect, record, and report accurate and verifiable data within applicable timeframe<br>• Transmit data to Data Management<br>• Perform query resolution<br>• Ensure compliance with electronic data requirements (e.g., passwords and access)<br>• Ensure access to source data by authorized parties, and protect confidentiality by preventing unauthorized access<br>• Manage study records retention and availability |
| Elements of and process for data query | |
| Reporting requirements for pharmacovigilance and/or product/device vigilance (e.g., CIOMS, IDMC/DSMB, safety databases) | |
| Essential Documents for the conduct of a clinical trial (e.g., paper/electronic, trial master file) | |
| Record retention, certified copy, and destruction practices and requirements | |
| Source data review (SDR) and source data verification (SDV) purpose and process | |
| Source documentation requirements | |
| Study documentation practices (Accurate, Legible, Complete, Original, Attributable, Contemporaneous, Consistent, Enduring, Available (ALCOA+)) | |