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OF CLINICAL RESEARCH PROFESSIONALS

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

(Effective 1 January 2017)

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 coordinator. View Executive Summary for the most recent Job Analysis Study

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Using the CCRC Detailed Content Outline (DCO)

The CCRC DCO was constructed from the results of the most recent (2015) 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	22%
III.	Product Development and Regulation	14%
IV.	Clinical Trial Operations (GCPs)	22%
V.	Study and Site Management	22%
VI.	Data Management and Informatics	12%
	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** (middle column) in the following six (6) content areas of clinical research. A CCRC typically uses this knowledge to perform the **tasks** listed (last column).

Content Area	CCRCs must demonstrate proficient knowledge within the following areas:	CCRCs typically perform the following tasks:
I. Scientific Concepts and Research Design (8%)	**1.1 elements of a protocol**	Identify and/or explain study objective(s) and endpoints
		Conduct prescreening activities with potential study subjects
		Screen trial subjects
	1.2 elements of an Investigational Brochure (IB) and/or investigational device use (instructions for use, user manual)	Identify and/or explain study design
		Identify and/or explain study objective(s) and endpoints
		Identify the safety and expected therapeutic effects of the investigational product using various study documents including the protocol and IB
	1.3 elements of and rationale for subject eligibility requirements	Identify and/or explain study objective(s) and endpoints
		Conduct prescreening activities with potential study subjects
		Screen trial subjects
	1.4 rationale for complying with a protocol	Identify and/or explain study objective(s) and endpoints
		Ensure compliance with study requirements and regulations
		Follow a study plan (e.g., management plan, monitoring plan, etc.)
	1.5 statistical principles	Identify and/or explain study design
		Maintain randomization procedures of investigational product

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Content Area	CCRCs must demonstrate proficient knowledge within the following areas:	CCRCs typically perform the following tasks:
		Collect, record, and report accurate and verifiable data
	1.6 study design characteristics (e.g., double-blind, crossover, randomized)	Identify and/or explain study design
		Maintain unblinding procedures of investigational product
		Evaluate study for feasibility (site determining ability to successfully conduct the study)
	1.7 study objective(s) and end points/outcomes	Identify and/or explain study design
		Identify and/or explain study objective(s) and endpoints
		Ensure and document follow-up medical care for study subjects, as applicable
	1.8 use of supplemental/rescue/comparator product in study design	Identify and/or explain study design
		Implement plan of action for management of adverse event(s) [e.g., stop investigational product, retest, treat subject]
		Ensure proper storage, dispensing, handling, and disposition of investigational product and related supplies
	1.9 treatment assignments (e.g., randomization, open label, registries)	Identify and/or explain study design
		Maintain randomization procedures of investigational product
		Instruct subjects on proper use of investigational product
2. Ethical and Participant Safety Considerations (22%)	**2.1 adverse events classification, documentation and reporting**	Maintain follow-up to determine resolution of adverse event(s)
		Ensure appropriate reporting and documentation of adverse event(s)
		Differentiate the types of adverse events that occur
	2.2 blinding procedures	Maintain unblinding procedures of investigational product
		Conduct unblinding procedures as applicable
		Dispense investigational product
	2.3 components of subject	Identify and/or explain study design

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Content Area	CCRCs must demonstrate proficient knowledge within the following areas:	CCRCs typically perform the following tasks:
	eligibility requirements	
		Conduct prescreening activities with potential study subjects
		Screen trial subjects
	2.4 confidentiality and privacy requirements	Comply with subject privacy regulations
		Ensure compliance with electronic data requirements (e.g., passwords and access)
		Ensure access to source data by authorized parties, and protect confidentiality by limiting unauthorized access
	2.5 elements of the IB	Identify the safety and expected therapeutic effects of the investigational product using various study documents including the protocol and IB
		Review the Investigators' Brochure
		Prepare and/or submit documents for IRB/IEC and/or sponsor review/approval
	2.6 elements of the informed consent form	Develop and/or review informed consent form
		Ensure IRB/IEC review/written approval of study and study documents
		Identify and/or maintain Essential Documents required for study conduct
	2.7 informed consent process requirements (e.g. paper, eConsent, assent)	Participate in and document the informed consent process(es)
		Ensure adequate consent and documentation of the informed consent process
		Comply with IRB/IEC requirements
	2.8 protection of human subjects	Assess subject safety during study participation
		Verify that investigational staff is qualified
		Minimize potential risks to subject safety
	2.9 protocol deviation/violation identification, documentation, and reporting processes	Ensure investigator/site protocol compliance
		Assess, manage, and/or review subject laboratory values, test results, and alerts
		Inform the sponsor and IRB/IEC of any deviations from the protocol and document as appropriate

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Content Area	CCRCs must demonstrate proficient knowledge within the following areas:	CCRCs typically perform the following tasks:
	2.10 recruitment plan/strategies (e.g. social media, digital, print, etc)	Document reasons for subject discontinuation (i.e., causes, contact efforts)
		Follow a study plan (e.g., management plan, monitoring plan, etc.)
		Re-evaluate the recruitment strategy as needed
	2.11 safety monitoring	Implement plan of action for management of adverse event(s) [e.g., stop investigational product, retest, treat subject]
		Oversee the management of safety risks at the site (e.g., clinical holds, product recalls)
		Create, document, and/or implement corrective and preventive action (CAPA) plans
	2.12 subject discontinuation criteria/procedures	Document reasons for subject discontinuation (i.e., causes, contact efforts)
		Comply with IRB/IEC requirements
		Implement plan of action for management of adverse event(s) [e.g., stop investigational product, retest, treat subject]
	2.13 subject retention strategies	Develop and/or implement study education plan and/or tools for subjects
		Re-evaluate the recruitment strategy as needed
		Prepare and/or submit documents for IRB/IEC and/or sponsor review/approval
	2.14 subject safety issues	Oversee the management of safety risks at the site (e.g., clinical holds, product recalls)
		Minimize potential risks to subject safety
		Escalate significant findings as appropriate
	2.15 vulnerable subject populations	Identify and/or address potential ethical issues involved with study conduct
		Ensure adequate consent and documentation of the informed consent process
		Participate in and document the informed consent process(es)

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Content Area	CCRCs must demonstrate proficient knowledge within the following areas:	CCRCs typically perform the following tasks:
	2.16 conflicts of interest in clinical research	Identify and/or address potential ethical issues involved with study conduct
		Identify and report potential fraud and misconduct
		Identify the role and proper composition of IRB/IECs
3. Product Development and Regulation (14%)	**3.1 audit and inspection processes (preparation, participation, documentation, and follow-up)**	Submit documents to regulatory authorities
		Prepare for and/or participate in audits and inspections
		Respond to or facilitate response to audit/inspection findings
	3.2 clinical development process (e.g., preclinical, clinical trial phases, device class)	Submit documents to regulatory authorities
		Evaluate study for feasibility (site determining ability to successfully conduct the study)
		Prepare and/or submit documents for IRB/IEC and/or sponsor review/approval
	3.3 clinical trial registries and requirements	Comply with IRB/IEC requirements
		Inform study subjects of trial results, in accordance with regulatory requirements
		Ensure consistency between the sites' standard operating procedures (SOPs) and the study requirements
	3.4 elements of fraud and misconduct	Identify and report potential fraud and misconduct
		Identify the role and proper composition of IRB/IECs
		Identify and/or address potential ethical issues involved with study conduct
	3.5 IRB/IEC reporting requirements	Prepare study summary and/or close-out letter for IRB/IEC
		Ensure compliance with study requirements and regulations
		Comply with IRB/IEC requirements
	3.6 IRB/IEC role, composition and purpose	Identify the role and proper composition of IRB/IECs
		Comply with IRB/IEC requirements

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Content Area	CCRCs must demonstrate proficient knowledge within the following areas:	CCRCs typically perform the following tasks:
		Coordinate protocol and/or protocol amendments through appropriate approval processes (e.g., IRB/IEC, sponsor, regulatory authority)
	3.7 protocol and protocol amendment submission and approval processes	Coordinate protocol and/or protocol amendments through appropriate approval processes (e.g., IRB/IEC, sponsor, regulatory authority)
		Implement protocol amendments
		Ensure IRB/IEC review/written approval of study and study documents
	3.8 regulatory reporting requirements	Prepare and/or submit documents for IRB/IEC and/or sponsor review/approval
		Inform the sponsor and IRB/IEC of any deviations from the protocol and document as appropriate
		Prepare and/or participate in close-out monitoring visit(s)
	3.9 safety reporting requirements	Follow standards for handling hazardous goods (e.g., International Air Transport Association (IATA)
		Ensure timely review of safety data
		Ensure appropriate reporting and documentation of adverse event(s)
	3.10 significant milestones in the evaluation of efficacy and safety (e.g., interim analysis result, DSMB review)	Create, document, and/or implement corrective and preventive action (CAPA) plans
		Ensure compliance with study requirements and regulations
		Prepare, and/or participate in interim monitoring activities (including onsite, remote, and risk-based)
4. Clinical Trial Operations (GCPs); (22%)	**4.1 delegation listing**	Verify that investigational staff is qualified
		Prepare and/or participate in study initiation activities
		Plan, conduct and/or participate in training of the investigational staff
	4.2 elements of an effective corrective and preventive action (CAPA) process(es) and plans	Create, document, and/or implement corrective and preventive action (CAPA) plans
		Identify issues and recommend investigator/site

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Content Area	CCRCs must demonstrate proficient knowledge within the following areas:	CCRCs typically perform the following tasks:
		corrective actions
		Minimize potential risks to subject safety
	4.3 elements of and rationale for monitoring plan(s)	Follow a study plan (e.g., management plan, monitoring plan, etc.)
		Ensure investigator/site protocol compliance
		Ensure monitoring activities are conducted according to plan
	4.4 indemnification/insurance requirements	Minimize potential risks to subject safety
		Identify and/or maintain Essential Documents required for study conduct
		Develop and/or review informed consent form
	4.5 monitoring activities (frequency of visits, data review, and follow up)	Ensure monitoring activities are conducted according to plan
		Prepare, and/or participate in interim monitoring activities (including onsite, remote, and risk-based)
		Document, communicate, and follow up on site visit findings
	4.6 pre-study/site selection visit activities	Evaluate study for feasibility (site determining ability to successfully conduct the study)
		Schedule, coordinate, and/or participate in pre-study site visit
		Ensure appropriate staff, facility, and equipment availability throughout the study
	4.7 principal investigator responsibilities	Ensure and document follow-up medical care for study subjects, as applicable
		Verify that investigational staff is qualified
		Review the Investigators' Brochure
	4.8 principles of risk based monitoring	Ensure monitoring activities are conducted according to plan
		Escalate significant findings as appropriate
		Prepare, and/or participate in interim monitoring activities (including onsite, remote, and risk-based)
	4.9 project feasibility	Evaluate study for feasibility (site determining

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	considerations	ability to successfully conduct the study)
		Ensure appropriate staff, facility, and equipment availability throughout the study
		Identify the safety and expected therapeutic effects of the investigational product using various study documents including the protocol and IB
	4.10 roles of various clinical trial entities (e.g., CROs, sponsors, regulatory authority, etc.)	Verify that investigational staff is qualified
		Escalate significant findings as appropriate
		Coordinate protocol and/or protocol amendments through appropriate approval processes (e.g., IRB/IEC, sponsor, regulatory authority)
	4.11 site close-out activities	Prepare and/or participate in close-out monitoring visit(s)
		Prepare study summary and/or close-out letter for IRB/IEC
		Manage study records retention and availability
	4.12 site initiation activities	Prepare and/or participate in study initiation activities
		Develop or participate in protocol training
		Facilitate site budget/contract approval process
	4.13 site selection criteria	Ensure appropriate staff, facility, and equipment availability throughout the study
		Verify that investigational staff is qualified
		Ensure consistency between the sites' standard operating procedures (SOPs) and the study requirements
	4.14 staff oversight	Ensure proper collection, processing, and shipment of specimens (e.g., centrifuge, preparation of slides, freezing, refrigeration)
		Ensure appropriate staff, facility, and equipment availability throughout the study
		Ensure investigator/site protocol compliance
	4.15 staff qualifications (site and monitor)	Verify that investigational staff is qualified
		Develop or participate in protocol training

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Content Area	CCRCs must demonstrate proficient knowledge within the following areas:	CCRCs typically perform the following tasks:
		Follow standards for handling hazardous goods (e.g., International Air Transport Association (IATA)
	4.16 staff training requirements	Develop or participate in protocol training
		Follow standards for handling hazardous goods (e.g., International Air Transport Association (IATA)
		Plan, conduct and/or participate in training of the investigational staff
	4.17 study close-out activities	Prepare and/or participate in close-out monitoring visit(s)
		Submit documents to regulatory authorities
		Reconcile investigational product and related supplies
5. Study and Site Management (22%)	**5.1 communication documentation requirements (e.g., telephone, email)**	Collect, record, and report accurate and verifiable data
		Maintain study related logs (e.g., site signature log, screening log)
		Develop source document templates
	5.2 contract budget negotiations and approval process	Participate in budget development
		Facilitate site budget/contract approval process
		Reconcile payments per contract (e.g. stipend payments)
	5.3 elements of a study budget	Participate in budget development
		Facilitate site budget/contract approval process
		Ensure appropriate staff, facility, and equipment availability throughout the study
	5.4 equipment and supplies use and maintenance	Perform and/or verify equipment calibration and maintenance
		Ensure proper collection, processing, and shipment of specimens (e.g., centrifuge, preparation of slides, freezing, refrigeration)
		Ensure adequacy of investigational product and other supplies at site

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Content Area	CCRCs must demonstrate proficient knowledge within the following areas:	CCRCs typically perform the following tasks:
	5.5 investigational product accountability and documentation requirements	Maintain accountability of investigational product
		Reconcile investigational product and related supplies
		Monitor investigational product expiration and/or manage resupply
	5.6 investigational product characteristics (e.g., mechanism of action, stability, product attributes, etc.)	Review the Investigators' Brochure
		Identify the safety and expected therapeutic effects of the investigational product using various study documents including the protocol and IB
		Ensure proper storage, dispensing, handling, and disposition of investigational product and related supplies
	5.7 investigational product labeling requirements	Prepare investigational product
		Dispense investigational product
		Monitor investigational product expiration and/or manage resupply
	5.8 investigational product packaging	Instruct subjects on proper use of investigational product
		Assess subject compliance
		Ensure proper storage, dispensing, handling, and disposition of investigational product and related supplies
	5.9 investigational product shipment	Ensure proper storage, dispensing, handling, and disposition of investigational product and related supplies
		Maintain accountability of investigational product
		Maintain study related logs (e.g., site signature log, screening log)
	5.10 investigational product storage	Ensure proper storage, dispensing, handling, and disposition of investigational product and related supplies
		Ensure appropriate staff, facility, and equipment availability throughout the study
		Maintain accountability of investigational product
	5.11 non-compliance management	Escalate significant findings as appropriate
		Oversee the management of safety risks at the site (e.g., clinical holds, product recalls)

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Content Area	CCRCs must demonstrate proficient knowledge within the following areas:	CCRCs typically perform the following tasks:
		Assess subject compliance
	5.12 project timelines (e.g. data lock, enrollment period, etc)	Follow a study plan (e.g., management plan, monitoring plan, etc.)
		Transmit data to Data Management
		Schedule subjects
	5.13 purpose of and process(es) for protocol compliance	Identify issues requiring protocol amendments
		Conduct subject visits
		Assess subject compliance
	5.14 sample collection, shipment, and storage requirements	Ensure appropriate staff, facility, and equipment availability throughout the study
		Manage study supplies (e.g., lab kits, case report forms)
		Follow standards for handling hazardous goods (e.g., International Air Transport Association (IATA)
	5.15 subject compliance assessment	Assess subject compliance
		Develop trial management tools (e.g. subject study calendar, source documents, retention material)
		Maintain accountability of investigational product
	5.16 subject responsibilities for study participation	Instruct subjects on proper use of investigational product
		Ensure adequate consent and documentation of the informed consent process
		Assess subject compliance
	5.17 subject visit activities	Schedule subjects
		Conduct subject visits
		Participate in and document the informed consent process(es)
	5.18 vendor management	Manage vendors (Obtain/verify vendor credentials,lab certification/licensure)
		Manage investigational product recall
		Ensure access to source data by authorized parties, and protect confidentiality by limiting unauthorized access

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Content Area	CCRCs must demonstrate proficient knowledge within the following areas:	CCRCs typically perform the following tasks:
6. Data Management and Informatics (12%)	**6.1 data management activities**	Review completed eCRF/CRF
		Transmit data to Data Management
		Manage study records retention and availability
	6.2 data privacy principles	Ensure compliance with electronic data requirements (e.g., passwords and access)
		Ensure access to source data by authorized parties, and protect confidentiality by limiting unauthorized access
		Comply with subject privacy regulations
	6.3 elements and purposes of data collection tools (e.g., eCRF, EDC)	Develop trial management tools (e.g. subject study calendar, source documents, retention material)
		Develop source document templates
		Evaluate data collection tools (e.g., case report form (e/CRF), electronic data capture (EDC)) for consistency with protocol
	6.4 elements of a final study report	Manage study records retention and availability
		Prepare study summary and/or close-out letter for IRB/IEC
		Prepare and/or participate in close-out monitoring visit(s)
	6.5 elements of and process for data query	Perform query resolution
		Collect, record, and report accurate and verifiable data
		Review completed eCRF/CRF
	6.6 elements of pharmacovigilance (e.g., CIOMS, IDMC/DSMB, safety databases)	Ensure timely review of safety data
		Collect, record, and report accurate and verifiable data
		Minimize potential risks to subject safety
	6.7 essential documents for the conduct of a clinical trial (e.g., paper/electronic, trial master file)	Identify and/or maintain Essential Documents required for study conduct
		Manage study records retention and availability
		Maintain study related logs (e.g., site signature log, screening log)
	6.8 record retention and destruction practices and requirements	Manage study records retention and availability
		Maintain study related logs (e.g., site signature log, screening log)

Content Area	CCRCs must demonstrate proficient knowledge within the following areas:	CCRCs typically perform the following tasks:
		Ensure consistency between the sites' standard operating procedures (SOPs) and the study requirements
	6.9 source data review (SDR) and source data verification (SDV) purpose and process	Collect, record, and report accurate and verifiable data
		Perform query resolution
		Ensure and document follow-up medical care for study subjects, as applicable
	6.10 source documentation requirements	Develop source document templates
		Collect, record, and report accurate and verifiable data
		Evaluate data collection tools (e.g., case report form (e/CRF), electronic data capture (EDC)) for consistency with protocol
	6.11 study documentation practices (accurate, complete, timely, legible, dated, and identify the trial)	Develop source document templates
		Evaluate data collection tools (e.g., case report form (e/CRF), electronic data capture (EDC)) for consistency with protocol
		Collect, record, and report accurate and verifiable data