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Certified Clinical Research Associate (CCRA®) Examination Detailed Content Outline

(Effective 1 January 2017)

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

Introduction

The CCRA program is accredited by the National Commission for Certifying Agencies (NCCA®). NCCA Accreditation is an impartial, third-party validation that the CCRA 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 CCRA 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 CCRA 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. View Executive Summary for the most recent Job Analysis Study.

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Using the CCRA Detailed Content Outline (DCO)

The CCRA 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 CCRA and therefore the content of the CCRA Exam. To be certified, a CRA 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	12%
II.	Ethical and Participant Safety Considerations	20%
III.	Product Development and Regulation	10%
IV.	Clinical Trial Operations (GCPs)	25%
V.	Study and Site Management	23%
VI.	Data Management and Informatics	10%
	Total	**100%**

Certified Clinical Research Associates (CCRAs) 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 CCRA DCO, below. Therefore, to prepare to take the CCRA Exam, one should study this outline and especially consider the underlying knowledge, skills, and abilities needed to perform as a CCRA. It is recommended that an eligible CCRA 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 CCRA® shall have proficient **knowledge** (middle column) in the following six (6) content areas of clinical research. A CCRA typically uses this knowledge to perform the **tasks** listed (last column).

Content Area	CCRAs must demonstrate proficient knowledge within the following areas:	CCRAs typically perform the following tasks:
I. Scientific Concepts and Research Design (12%)	**1.1 components of a product development plan (e.g., timelines)**	Review background information (e.g., product development plan, IB)
		Identify and/or explain study objective(s) and endpoints
		Identify the expected or unexpected results associated with investigational products
	1.2 elements of a protocol	Identify and/or explain study design
		Identify issues requiring protocol amendments
		Develop and/or Evaluate data collection tools (e.g., case report form (e/CRF), electronic data capture (EDC)) for consistency with protocol
	1.3 elements of an Investigational Brochure (IB) and/or investigational device use (instructions for use)	Identify the safety and expected therapeutic effects of the investigational product.
		Review background information (e.g., product development plan, IB)
		Identify the expected or unexpected results associated with investigational products
	1.4 elements of and rationale for subject eligibility requirements	Develop and/or follow a recruitment strategy
		Evaluate study for feasibility (site determining ability to successfully conduct the study)
		Re-evaluate the recruitment strategy as needed
	1.5 rationale for complying with a protocol	Develop or participate in protocol training
		Ensure compliance with study requirements and regulations
		Ensure investigator/site protocol compliance
	1.6 study design characteristics (e.g.,	Identify and/or explain study design

Content Area	CCRAs must demonstrate proficient knowledge within the following areas:	CCRAs typically perform the following tasks:
	double-blind, crossover, randomized)	Identify and/or explain study objective(s) and endpoints
		Develop and/or follow a study plan (e.g., management plan, monitoring plan, etc.)
	1.7 study objective(s) and end points/outcomes	Identify and/or explain study objective(s) and endpoints
		Plan, conduct and/or participate in training of the investigational staff
		Develop and/or Evaluate data collection tools (e.g., case report form (e/CRF), electronic data capture (EDC)) for consistency with protocol
	1.8 use of supplemental/rescue/comparator product in study design	Identify and/or explain study design
		Minimize potential risks to subject safety
		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
		Ensure adequacy of investigational product and other supplies at site
		Monitor investigational product expiration and/or manage resupply
2. Ethical and Participant Safety Considerations (20%)	**2.1 adverse events classification, documentation and reporting**	Differentiate the types of adverse events that occur
		Maintain follow-up to determine resolution of adverse event(s)
		Verify appropriate reporting and documentation of adverse event(s)
	2.2 blinding procedures	Ensure proper storage, dispensing, handling, and disposition of investigational product and related supplies
		Identify and/or explain study design
		Identify and/or explain study objective(s) and endpoints

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Content Area	CCRAs must demonstrate proficient knowledge within the following areas:	CCRAs typically perform the following tasks:
	2.3 components of subject eligibility requirements	Assess, manage, and/or review subject laboratory values, test results, and alerts
		Plan, conduct and/or participate in training of the investigational staff
		Inform the sponsor and IRB/IEC of any deviations from the protocol and document as appropriate
	2.4 confidentiality and privacy requirements	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
	2.5 elements of the IB	Identify the safety and expected therapeutic effects of the investigational product.
		Differentiate the types of adverse events that occur
		Review the Investigators' Brochure
	2.6 elements of the informed consent form	Ensure adequate consent and documentation
		Develop and/or review informed consent form
		Prepare and/or submit documents for IRB/IEC and/or sponsor review/approval
	2.7 informed consent process requirements	Verify adequate implementation and documentation of the informed consent process
		Identify and/or address potential ethical issues involved with study conduct
		Prepare the study site for audits and inspections
	2.8 protection of human subjects	Minimize potential risks to subject safety
		Assess, manage, and/or review subject laboratory values, test results, and alerts

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Content Area	CCRAs must demonstrate proficient knowledge within the following areas:	CCRAs typically perform the following tasks:
		Assess subject safety during study participation
	2.9 protocol deviation/violation identification, documentation, and reporting processes	Inform the sponsor and IRB/IEC of any deviations from the protocol and document as appropriate
		Prepare for and/or participate in audits and inspections
		Identify issues and recommend investigator/site corrective actions
	2.10 recruitment plan/strategies	Re-evaluate the recruitment strategy as needed
		Develop and/or follow a recruitment strategy
		Verify investigator/site feasibility
	2.11 safety monitoring	Ensure timely review of safety data
		Reconcile safety and clinical databases
		Assess subject safety during study participation
	2.12 subject discontinuation criteria/procedures	Document reasons for subject discontinuation (i.e., causes, contact efforts)
		Assess subject compliance
		Minimize potential risks to subject safety
	2.13 subject retention strategies	Develop and/or implement study education plan and/or tools for subjects
		Develop project/trial management tools
		Select trial sites for participation
	2.14 subject safety issues	Maintain follow-up to determine resolution of adverse event(s)
		Oversee the management of safety risks (e.g., clinical holds, product recalls)
		Assess subject safety during study participation
	2.15 vulnerable subject populations	Identify and/or address potential ethical issues involved with study conduct
		Comply with IRB/IEC requirements
		Ensure adequate consent and documentation
	2.16 conflicts of interest in clinical research	Identify and/or address potential ethical issues involved with study conduct

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Content Area	CCRAs must demonstrate proficient knowledge within the following areas:	CCRAs typically perform the following tasks:
		Identify and report potential fraud and misconduct
		Investigate potential fraud and misconduct
3. Product Development and Regulation (10%)	**3.1 audit and inspection processes (preparation, participation, documentation, and follow-up)**	Prepare the study site for audits and inspections
		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)	Ensure compliance with study requirements and regulations
		Coordinate protocol and/or protocol amendments through appropriate approval processes (e.g., IRB/IEC, sponsor, regulatory authority)
		Prepare and/or submit documents for IRB/IEC and/or sponsor review/approval
	3.3 elements of fraud and misconduct	Identify and/or address potential ethical issues involved with study conduct
		Identify and report potential fraud and misconduct
		Investigate potential fraud and misconduct
	3.4 IRB/IEC reporting requirements	Comply with IRB/IEC requirements
		Ensure IRB/IEC review/written approval of study and study documents
		Prepare and/or submit documents for IRB/IEC and/or sponsor review/approval
	3.5 IRB/IEC role, composition and purpose	Identify the role and proper composition of IRB/IECs
		Ensure IRB/IEC review/written approval of study and study documents
		Inform the sponsor and IRB/IEC of any deviations from the protocol and document as appropriate

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Content Area	CCRAs must demonstrate proficient knowledge within the following areas:	CCRAs typically perform the following tasks:
	3.6 product development lifecycle	Review background information (e.g., product development plan, IB)
		Identify the safety and expected therapeutic effects of the investigational product.
		Manage study records retention and availability
	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)
		Identify issues requiring protocol amendments
		Implement protocol amendments
	3.8 regulatory reporting requirements	Ensure compliance with study requirements and regulations
		Inform the sponsor and IRB/IEC of any deviations from the protocol and document as appropriate
		Verify appropriate reporting and documentation of adverse event(s)
	3.9 safety reporting requirements	Verify appropriate reporting and documentation of adverse event(s)
		Differentiate the types of adverse events that occur
		Oversee the management of safety risks (e.g., clinical holds, product recalls)
	3.10 significant milestones in the evaluation of efficacy and safety (e.g., interim analysis result, DSMB review)	Ensure timely review of study data
		Develop and/or follow a study plan (e.g., management plan, monitoring plan, etc.)
		Ensure timely review of safety data
4. Clinical Trial Operations (GCPs); (25%)	**4.1 delegation of responsibilities**	Select qualified investigational staff
		Verify that investigational staff is qualified
		Develop or participate in protocol training
	4.2 elements of an effective corrective and preventive action	Create, document, and/or implement corrective and preventive action (CAPA) plans

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Content Area	CCRAs must demonstrate proficient knowledge within the following areas:	CCRAs typically perform the following tasks:
	(CAPA) plan	Document, communicate, and follow up on site visit findings
		Escalate significant findings as appropriate
	4.3 elements of and rationale for monitoring plan(s)	Develop and/or follow a study plan (e.g., management plan, monitoring plan, etc.)
		Develop and implement monitoring guidelines/plans
		Prepare, conduct, and/or participate in interim monitoring visit(s)
	4.4 elements of the investigator's brochure	Perform risk-based monitoring activities
		Assess, manage, and/or review subject laboratory values, test results, and alerts
		Review the Investigators' Brochure
	4.5 monitoring activities (source data review, source data verification)	Conduct co-monitoring/training visits
		Perform onsite monitoring activities
		Perform remote monitoring activities
	4.6 pre-study/site selection visit activities	Obtain/verify vendor credentials (e.g., lab certification/licensure)
		Schedule, coordinate, and/or participate in pre-study site visit
		Select trial sites for participation
	4.7 principal investigator responsibilities	Monitor accountability of investigational product
		Ensure appropriate staff, facility, and equipment availability throughout the study
		Identify and/or maintain Essential Documents required for study conduct
	4.8 principles of risk based monitoring	Perform risk-based monitoring activities
		Conduct source data review (SDR) and/or source data verification (SDV) remotely
		Ensure monitoring activities are conducted according to plan
	4.9 project feasibility considerations	Ensure consistency between the sites' standard operating procedures (SOPs) and the

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Content Area	CCRAs must demonstrate proficient knowledge within the following areas:	CCRAs typically perform the following tasks:
		study requirements
		Evaluate study for feasibility (site determining ability to successfully conduct the study)
		Select trial sites for participation
	4.10 roles of various clinical trial entities (e.g., CROs, sponsors, regulatory authority, etc.)	Develop and/or follow a study plan (e.g., management plan, monitoring plan, etc.)
		Identify the role and proper composition of IRB/IECs
		Obtain/verify vendor credentials (e.g., lab certification/licensure)
	4.11 site close-out activities	Prepare, conduct, and/or participate in close-out monitoring visit(s)
		Transmit data to Data Management
		Reconcile investigational product and related supplies
	4.12 site initiation activities	Prepare, conduct and/or participate in study initiation activities
		Perform and/or verify equipment calibration and maintenance
		Verify Essential Documents required for study conduct
	4.13 site selection criteria	Ensure consistency between the sites' standard operating procedures (SOPs) and the study requirements
		Select qualified investigational staff
		Select trial sites for participation
	4.14 staff oversight	Review study related logs (e.g., site signature log, screening log)
		Verify that investigational staff is qualified
		Ensure consistency between the sites' standard operating procedures (SOPs) and the

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Content Area	CCRAs must demonstrate proficient knowledge within the following areas:	CCRAs typically perform the following tasks:
		study requirements
	4.15 staff qualifications (site and monitor)	Verify that investigational staff is qualified
		Develop or participate in protocol training
		Follow standards for handling hazardous goods (e.g., International Air Transport Association (IATA)
	4.16 staff training requirements	Develop or participate in protocol training
		Plan, conduct and/or participate in training of the investigational staff
		Ensure proper collection, processing, and shipment of specimens (e.g., centrifuge, preparation of slides, freezing, refrigeration)
	4.17 study close-out activities	Perform query resolution
		Verify Essential Documents required for study conduct
		Prepare, conduct, and/or participate in close-out monitoring visit(s)
5. Study and Site Management (23%)	**5.1 communication documentation requirements (e.g., telephone, email)**	Document, communicate, and follow up on site visit findings
		Perform remote monitoring activities
		Escalate significant findings as appropriate
	5.2 corrective and preventive action (CAPA) process(es) and plans	Create, document, and/or implement corrective and preventive action (CAPA) plans
		Escalate significant findings as appropriate
		Identify issues and recommend investigator/site corrective actions
	5.3 equipment and supplies use and maintenance	Manage study supplies (e.g., lab kits, case report forms)
		Ensure adequacy of investigational product and other supplies at site

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Content Area	CCRAs must demonstrate proficient knowledge within the following areas:	CCRAs typically perform the following tasks:
		Perform and/or verify equipment calibration and maintenance
	5.4 investigational product accountability and documentation requirements	Monitor accountability of investigational product
		Manage investigational product recall
		Reconcile investigational product and related supplies
	5.5 investigational product characteristics (e.g., mechanism of action, stability, etc.)	Identify the expected or unexpected results associated with investigational products
		Ensure proper storage, dispensing, handling, and disposition of investigational product and related supplies
		Monitor investigational product expiration and/or manage resupply
	5.6 investigational product labeling requirements	Monitor investigational product expiration and/or manage resupply
		Reconcile investigational product and related supplies
		Identify and/or maintain Essential Documents required for study conduct
	5.7 investigational product packaging	Monitor investigational product expiration and/or manage resupply
		Reconcile investigational product and related supplies
		Ensure proper storage, dispensing, handling, and disposition of investigational product and related supplies
	5.8 investigational product reference materials (e.g., Investigational brochure, instructions for use, user manual)	Review the Investigators' Brochure
		Develop and/or implement study education plan and/or tools for subjects
		Identify the safety and expected therapeutic effects of the investigational product.

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Content Area	CCRAs must demonstrate proficient knowledge within the following areas:	CCRAs typically perform the following tasks:
	5.9 investigational product shipment	Ensure proper storage, dispensing, handling, and disposition of investigational product and related supplies
		Manage investigational product recall
		Ensure adequacy of investigational product and other supplies at site
	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
		Review study related logs (e.g., site signature log, screening log)
	5.11 non-compliance management	Identify and report potential fraud and misconduct
		Ensure investigator/site protocol compliance
		Escalate significant findings as appropriate
	5.12 project timelines	Develop and/or follow a study plan (e.g., management plan, monitoring plan, etc.)
		Develop project/trial management tools
		Evaluate study for feasibility (site determining ability to successfully conduct the study)
	5.13 purpose of and process(es) for protocol compliance	Ensure investigator/site protocol compliance
		Perform onsite monitoring activities
		Ensure proper collection, processing, and shipment of specimens (e.g., centrifuge, preparation of slides, freezing, refrigeration)
	5.14 roles of various clinical trial entities (e.g., CROs, sponsors, regulatory authority, etc.)	Identify the role and proper composition of IRB/IECs
		Escalate significant findings as appropriate
		Respond to or facilitate response to audit/inspection findings

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Content Area	CCRAs must demonstrate proficient knowledge within the following areas:	CCRAs typically perform the following tasks:
	5.15 sample collection, shipment, and storage requirements	Ensure proper collection, processing, and shipment of specimens (e.g., centrifuge, preparation of slides, freezing, refrigeration)
		Perform and/or verify equipment calibration and maintenance
		Review study related logs (e.g., site signature log, screening log)
	5.16 subject compliance assessment	Assess subject compliance
		Ensure investigator/site protocol compliance
		Develop and/or implement study education plan and/or tools for subjects
	5.17 subject responsibilities for study participation	Develop and/or Evaluate data collection tools (e.g., case report form (e/CRF), electronic data capture (EDC) for consistency with protocol
		Verify adequate implementation and documentation of the informed consent process
		Document reasons for subject discontinuation (i.e., causes, contact efforts)
	5.18 subject visit activities	Assess subject compliance
		Reconcile investigational product and related supplies
		Develop project/trial management tools
6. Data Management and Informatics (10%)	**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

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Content Area	CCRAs must demonstrate proficient knowledge within the following areas:	CCRAs typically perform the following tasks:
	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 and process for data query	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 pharmacovigilance (e.g., CIOMS, IDMC/DSMB, safety databases)	Perform query resolution
		Collect, record, and report accurate and verifiable data
		Review completed eCRF/CRF
	6.6 essential documents for the conduct of a clinical trial (e.g., trial master file)	Ensure timely review of safety data
		Collect, record, and report accurate and verifiable data
		Minimize potential risks to subject safety
	6.7 record retention and destruction practices and requirements	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 source data review (SDR) and source data verification (SDV) purpose and process	Manage study records retention and availability
		Maintain study related logs (e.g., site signature log, screening log)
		Ensure consistency between the sites' standard operating procedures (SOPs) and the study requirements
	6.9 source documentation	Collect, record, and report accurate and

Content Area	CCRAs must demonstrate proficient knowledge within the following areas:	CCRAs typically perform the following tasks:
	requirements	verifiable data
		Perform query resolution
		Ensure and document follow-up medical care for study subjects, as applicable
	6.10 study documentation practices (accurate, complete, timely, legible, dated, and identify the trial)	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