ACADEMY
OF CLINICAL RESEARCH PROFESSIONALS

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

(Effective October 2019)

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.

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Using the CCRA Detailed Content Outline (DCO)

The CCRA 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 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	8%
II.	Ethical and Participant Safety Considerations	20%
III.	Product Development and Regulation	10%
IV.	Clinical Trial Operations (GCPs)	25%
V.	Study and Site Management	25%
VI.	Data Management and Informatics	12%
	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).

Domain I – Scientific Concepts and Research Design – 8% of exam	
Knowledge Statements	**Tasks**
Elements of a protocol	• Review background information and rational (e.g. product development plan, IB, therapeutic area, history) • Identify and/or explain standard of care versus research • Identify and/or explain study design (e.g. key protocol elements and rationale, blinding, randomization) • Identify and/or explain study objective(s) and endpoints
Elements of an investigational brochure (IB) and/or investigational device use (instructions for use)	
Elements of and rational for subject eligibility requirements	
Rationale for complying with a protocol	
Study design characteristics (e.g. double-blind, crossover, randomized)	
Study objective(s) and end points/outcomes	
Use of supplemental/rescue/comparator product in study design	
Treatment assignments (e.g. randomization, open label, registries)	
Therapeutic area and/or available learning resources (e.g. standard of care versus research	
Domain II – Ethical and Participant Safety Considerations – 20% of exam	
Knowledge Statements	**Tasks**
Adverse events classification, documentation, and reporting	• Ensure site's compliance with IRB/IEC requirements and other ethical considerations (e.g. Declaration of Helsinki, Belmont Report) • Identify the safety and expected therapeutic effects of the investigational product/device • Develop and/or follow a recruitment strategy that complies with ethical considerations • Recognize subject confidential information • Comply with subject privacy regulations (e.g.
Blinding/unblinding procedures	
Components of subject eligibility requirements	
Confidentiality and privacy requirements	
Components of the safety profile	
Elements of the informed consent form	
Informed consent process requirements	
Protection of human subjects (e.g. IRB/IEC requirements, Declaration of Helsinki, subject	

compensation) Protocol deviation/violation identification, documentation, and reporting processes Recruitment plan/strategies Safety monitoring Subject discontinuation criteria/procedures Subject retention strategies Vulnerable subject populations Conflicts of interest in clinical research Elements of fraud and misconduct	HIPPA, GDPR) • Develop and/or review informed consent • Ensure and verify adequate implementation and documentation of the informed consent process • Ensure subject eligibility meets protocol inclusion/exclusion criteria at enrollment and during study conduct • Develop and/or implement study education plan and/or tools for sites • Ensure Investigator assessment and management of subject laboratory values, test results, and alerts • Identify and/or verify appropriate reporting and documentation of adverse events(s) to resolution • Ensure timely review of safety data by site and sponsor • Verify the site's management of safety risks (e.g. clinical holds, product recalls, DSMB/IDMC) • Ensure adequate documentation of subject discontinuation (i.e. causes, contact efforts) • Identify and report potential fraud and misconduct
Domain III – Product Development and Regulation – 10% of exam	
Knowledge Statements	**Tasks**
Product development (e.g. timelines, preclinical, phases, regulatory strategy, life cycle) IRB/IEC reporting requirements and communication IRB/IEC purpose, role, and composition Protocol and protocol amendment submission and approval processes Regulatory authority reporting requirements and communication Safety reporting requirements Significance of milestones in the evaluation of efficacy and safety (e.g. interim analysis results, DSMB, review)	• Identify the role and proper composition of IRB/IECs • Prepare and/or submit documents for IRB/IEC review/approval • Ensure IRB/IEC review/written approval of study and study documents • Inform the sponsor and ensure IRB/IEC submission of any deviations from the protocol and document as appropriate • Ensure compliance with study requirements and regulations • Prepare for and/or participate in audits and inspections

	• Respond to or facilitate response to audit/inspection findings
Domain IV – Clinical Trial Operations (GCP) – 25% of exam	
Knowledge Statements	**Tasks**
Delegation of responsibilities Elements of an effective root cause analysis and corrective and preventive action (CAPA) plan Elements of and rationale for monitoring plan(s) Elements of the investigator's brochure (IB) Monitoring responsibilities (e.g. purpose, extent, procedures) Principals of risk-based monitoring Project feasibility considerations Responsibilities of various clinical trial entities/personnel (e.g. CROs, sponsors, regulatory authority, data manager) Audits and inspection processes (preparation, participation, documentation, and follow up) Pre-study activities Site selection activities Site initiation activities Interim visit activities Site close-out activities Study completion activities Staff qualifications activities Staff/study team training requirements Essential documents (e.g. Trial Master File, Investigative Site File)	• Coordinate protocol and/or protocol amendments through appropriate approval processes (e.g. IRB/IEC, sponsor, regulatory authority) • Facilitate compliance between the sites' standard operating procedures (SOPs) and the study requirements • Verify tat investigational staff is qualified (e.g. CV, medical license, GCP qualifications) • Ensure adequate Principal Investigator oversight • Develop protocol and/or amendments training • Identify and communicate issues potentially requiring protocol amendments • Develop/update project/trial management tools • Develop monitoring guidelines/plans • Schedule, coordinate, and/or pre-study site visit(s) • Prepare, conduct and/or participate in site initiation, on-site monitoring, remote monitoring, risk-based, close out and co-monitoring/training visit(s) • Ensure source documentation adheres to ALCOA-CCEA principles • Ensure investigator/site protocol compliance • Document, communicate, and follow up on site visit activities and/or findings • Escalate significant findings as appropriate • Create, document, and/or implement root cause analysis and /or CAPA plans to completion • Maintain Trial Master File • Review and reconcile Investigator Site File (e.g. essential documents, logs) and Trial

	Master File
Domain V – Study and Site Management – 25% of exam	
Knowledge Statements	**Tasks**
Communication documentation requirements (e.g. phone, email) Equipment and supplies use and maintenance Investigational product/device management (e.g. accountability, dispensing, shipment, storage, and documentation requirements) Investigational product/device characteristics (e.g. mechanism of action, stability, etc) Investigational product/device labeling and packaging requirements Investigational product/deice reference materials Study timelines Purpose, processes, and management of protocol compliance/non-compliance Roles of various clinical trial entities/plan (e.g. medical monitor, vendors, IRR/IEC, sponsor, CRO) Sample/diagnostic collection, shipment verification, reporting and storage requirements Subject compliance assessment Subject responsibilities for study participation Contracts and budgets (e.g. subject compensation, site payment) Study vendors	• Act as the main source of communication between site and sponsor • Evaluate trial sties for participation • Follow study plans (e.g. monitoring plan, communication plan) • Obtain/verify vendor credentials (e.g. lab certification/licensure) • Coordinate access to study systems (e.g. vendor portals, IVRS) • Facilitate/verify translation of study documents • Verify investigator/site feasibility (e.g. personnel and facilities) • Prepare, conduct, and/or participate in study initiation activities (e.g. kick-off meeting, investigator meeting, essential document collection) • Plan, conduct, verify, and/or participate in training of the investigational staff • Assess subject compliance • Re-evaluate the recruitment strategy as needed • Manage study supplies (e.g. lab kits, case report forms, study related devices) • Verify equipment calibration and maintenance • Ensure proper collection, processing, and shipment of specimens (e.g. centrifuge, preparation of slides, freezing, refrigeration) • Monitor appropriate staff, facility, and equipment availability throughout the study • Identify issues and recommend investigatory/site corrective actions • Ensure adequacy of investigational product/device and associated supplies • Ensure proper storage, dispensing, handling and disposition of investigational

	product/device and associated supplies • Reconcile investigational product/device and associated supplies • Manage investigational product/device recall/quarantine • Monitor investigational product/device expiration, manage resupply and/or relabeling
Domain VI – Data Management and Informatics – 12% of exam	
Knowledge Statements	**Tasks**
Data management activities	• Develop and/or review CRF/eCRF completion guidelines • Develop and/or evaluate data collection tools (e.g. case report form (e/CRF), diaries and other collection devices) for consistency with protocol • Perform CRF/eCRF user acceptance testing • Transmit data to Data Management • Identify location of source documentation • Conduct source data review (SDR) and/or source data verification (SDV) • Ensure timely data entry and review • Review, clarify and obtain data changes from sites • Issue and resolve data queries • Facilitate Investigator CRF/eCRF signatures and database lock • Review data for trends (e.g. central monitoring, data listing review) • 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 • Reconcile safety and clinical databases • Manage study records retention and availability
Data privacy principles and access to site/subject records	
Elements and purposes of data collection tools (e.g. CRF/eCRF, patient reported outcome devices)	
Elements of and process for data query (e.g. query writing)	
Elements of pharmacovigilance (e.g. CIOMS, IDMC/DSMB, safety databases)	
Record retention and destruction practices and requirements	
Source data review (SDR) and source data verification (SDV) purpose and process	
Source documentation requirements (e.g. ALCOA-CCEA)	