ACADEMY
OF CLINICAL RESEARCH PROFESSIONALS

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

(Effective October 2019)

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

Introduction

The CPI program is accredited by the National Commission for Certifying Agencies (NCCA®). NCCA Accreditation is an impartial, third-party validation that the CPI 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 CPI 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 CPI 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 CPI Detailed Content Outline (DCO)

The CPI 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	18%
II.	Ethical and Participant Safety Considerations	24%
III.	Product Development and Regulation	13%
IV.	Clinical Trial Operations (GCPs)	21%
V.	Study and Site Management	14%
VI.	Data Management and Informatics	10%
	Total	**100%**

Certified Principal Investigators (CPIs) 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 CPI DCO, below. Therefore, to prepare to take the CPI Exam, one should study this outline and especially consider the underlying knowledge, skills, and abilities needed to perform as a CPI. It is recommended that an eligible CPI Exam candidate use this outline to identify knowledge gaps for constructing a relevant preparation plan.

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Detailed Content Outline

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

Domain I – Scientific Concepts and Research Design – 18% of exam	
Knowledge Statements	**Tasks**
Elements of an Investigational Brochure (IB) and/or investigational device use (instructions for use) Elements of a protocol Study objective(s) and end points/outcomes Elements of, and rationale for, subject eligibility requirements Investigational product characteristics (e.g., mechanism of action, stability, etc.) Statistical principles (e.g. confidence interval, study power) Study design characteristics (e.g., double-blind, crossover, randomized) Treatment assignments (e.g., randomization, open label) Supplemental/rescue/comparator/placebo product(s) in study design	• Develop the protocol (e.g., inclusion/exclusion criteria, procedures, schedule of events, safety and efficacy parameters, hypothesis generation) • Evaluate protocol for scientific soundness (e.g., risk, benefit, validity of study procedures, endpoints) • Evaluate protocol for feasibility (in terms of practicality of execution, not site-specific considerations) • Review background information (e.g., study concept, product development plan, IB, target product profile, mechanism of action) • Identify and/or explain study design • Identify the expected or unexpected results associated with investigational products • Critically analyze and/or explain study results (e.g., journal article, IB, clinical study report)
Domain II – Ethical and Participant Safety Considerations – 24% of exam	
Knowledge Statements	**Tasks**
Protection of human subjects Vulnerable subject populations Confidentiality and privacy requirements Conflicts of interest The IB (e.g., safety information, toxicology, literature review, guidance to the investigator) Recruitment and retention strategies Elements of the informed consent form	• Identify the safety and expected therapeutic effects of the IP by verifying the preclinical and clinical research performed to date (using the IB) • Develop, manage, and/or implement ethical recruitment and retention strategies • Develop, modify, and/or review informed consent form

Informed consent process requirements Initial subject eligibility requirements (e.g., inclusion, exclusion criteria) Blinding/unblinding procedures Safety monitoring Adverse events classification, documentation and reporting Subject discontinuation or withdrawal criteria/procedures Protocol deviation/violation identification, documentation, and reporting processes	• Conduct prescreening activities with potential study subjects according to SOPs • Screen trial subjects according to protocol and ICH guidelines • Comply with subject privacy regulations (e.g. report data breach) • Ensure adequate informed consent and documentation (incl. vulnerable populations such as inmates, children, pregnant women, etc.) • Develop, ensure and/or oversee study education plan and/or tools for subjects • Ensure and document follow-up medical care for study subjects, as applicable • Assess, manage, and/or review subject laboratory values, test results, and alerts • Differentiate the types of adverse events that occur • Implement plan of action for management of adverse event(s) [e.g., stop investigational product, retest, treat subject] • Assess AE causality, severity, and seriousness • Maintain follow-up to determine resolution of adverse event(s) • Verify appropriate reporting and documentation of adverse event(s) • Ensure timely review of safety data • Assess subject safety during study participation (e.g. protocol deviation) • Oversee the management of safety risks (e.g., clinical holds, product recalls, product contamination) • Conduct unblinding procedures as applicable • Document reasons for subject discontinuation/withdrawal/termination (e.g., adverse event, family emergency, subject preference) • Identify and/or address potential ethical issues involved with study conduct • Identify and report potential fraud and misconduct

	• Inform study subjects of trial risks, modifications, and results, in accordance with regulatory requirements
Domain III – Product Development and Regulation – 13% of exam	
Knowledge Statements	**Tasks**
Product development process (e.g., non-clinical, clinical trial phases, device class) IRB/IEC role, composition and purpose IRB/IEC reporting requirements Regulatory reporting requirements Submission and approval process (e.g., protocols, protocol amendments, ICFs, ICF amendments, IB, and IB amendments) Local reporting requirements Elements of fraud and misconduct Audit and inspection processes (e.g., preparation, participation, documentation, and follow-up) Significant milestones in the evaluation of efficacy and safety (e.g., interim analysis result, DSMB review)	• Comply with regulatory requirements (e.g. IRB/IEC) • Identify the role and proper composition of regulatory bodies (e.g. IRB/IECs) • Prepare and/or submit documents for regulatory bodies (e.g. IRB/IEC) and/or sponsor review/approval • Ensure regulatory body (e.g. IRB/IEC) review/written approval of study and study documents • Timely inform the sponsor and regulatory body (e.g. IRB/IEC) of any deviations from the protocol and document as appropriate • Prepare or review study summary and/or close-out letter for regulatory body (e.g. IRB/IEC) • Evaluate need to modify/terminate study based on efficacy, safety, or logistical concerns • Ensure compliance with study requirements and regulations • Submit documents to regulatory bodies as applicable • Develop, update, and/or review the Investigators' Brochure • Prepare for and/or participate in audits and inspections • Respond to or facilitate response to audit/inspection findings • Follow standards for handling hazardous materials (e.g., International Air Transport Association (IATA))

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Domain IV – Clinical Trial Operations (GCP) – 21% of exam	
Knowledge Statements	**Tasks**
Project feasibility assessment (e.g. site demographics, patient populations, staff and equipment) Principal investigator responsibilities (e.g. safety, quality, data integrity) Indemnification/insurance requirements Delegation of duties Staff training requirements (both protocol and non-protocol-specific) Site initiation activities Staff oversight Principles of study monitoring (e.g., risk based, full SDV, remote, reporting requirements, etc.) Principles of quality management system (including CAPA plans) Communication documentation policies (e.g., telephone, email, mail, written verification of oral instructions, etc.) Subject compliance assessment Site close-out activities	• Evaluate site for study feasibility • Supervise coordination of protocol and/or protocol amendments through appropriate approval processes (e.g., IRB/IEC, sponsor, regulatory authorities) • Ensure consistency between the sites' standard operating procedures (SOPs) and the study requirements • Select qualified investigational staff • Delegate study-related roles and responsibilities as appropriate • Develop and/or participate in protocol training • Identify issues requiring protocol amendments • Implement protocol amendments after appropriate approval • Ensure investigator/site protocol compliance • Document and/or follow up on site visit findings • Implement and assure quality management system • Create, document, and/or implement corrective and preventive action (CAPA) plans • Prepare, conduct, and/or participate in monitoring visit(s) (e.g., close-out, pre-study, interim, risk-based)
Domain V – Study and Site Management – 14% of exam	
Knowledge Statements	**Tasks**
Roles of various clinical trial entities and local ordinances (e.g., CROs, sponsors, regulatory bodies, IRB, fire regulations, building codes, SMOs, PHC, data management and coordination center, etc.) Elements of a study budget Contract budget negotiations and approval process Study timelines (preparatory, during, and post)	• Ensure vendors are qualified (e.g. obtain lab certification/licensure) • Facilitate site budget/contract approval process • Obtain, verify, negotiate, and/or manage site/ investigator indemnification/ insurance • Prepare, conduct and/or participate in study

Investigational product reference materials (e.g., Investigational Brochure, instructions for use, user manual) Investigational product storage and shipment Investigational product accountability and documentation requirements Equipment and supplies use and maintenance (e.g. calibration schedules, expiration dates) Sample collection, shipment, and storage requirements Subject responsibilities for study participation Subject visit activities IT infrastructure needs (e.g., validation, electronic signatures, audit trail) Purpose of and process(es) for protocol compliance (e.g., regulatory requirements, data integrity)	initiation activities • Plan, conduct, and/or participate in training of the investigational staff (e.g. safety, protocol) • Schedule/perform/oversee subject visits as appropriate • Educate subjects on proper use of investigational product • Assess subject compliance • Re-evaluate recruitment strategy as needed • Ensure and maintain appropriate staff, facility, supplies, and equipment throughout study (e.g. calibration, case report forms, retention sampling) • Identify site issues and recommend corrective actions • Comply with randomization and blinding/unblinding procedures for investigational product (including initial assignment and ongoing maintenance) • Ensure proper IP management (e.g. preparation, storage, dispensing, handling, disposition, accountability, recall, retention sampling, and reconciliation)
Domain VI – Data Management and Informatics – 10% of exam	
Knowledge Statements	**Tasks**
Essential documents for the conduct of a clinical trial (e.g., contents of trial master file) Elements and purposes of data collection tools (e.g., eCRF, EDC) Data privacy principles (e.g., redacting and blinding personal information, background checks) Study documentation practices (e.g., accurate, complete, timely, legible, dated, and identification of the trial) Source data review (SDR) and source data verification (SDV) purpose and process Data management principles (e.g. security, backup) and tools (e.g., IWRS, IVRS)	• Ensure proper source documentation • Review and approve completed eCRF/CRF • Identify, verify, and/or maintain Essential Documents required for study conduct • Collect, record, and report accurate and verifiable data (e.g., weight bills, certificate of analysis, study-related logs) by use of appropriate data acquisition methods (e.g., analogue, digital) • Ensure timely review of study data • Timely perform or supervise query resolution • Ensure compliance with electronic data requirements (e.g., passwords and access)

Record retention and destruction practices and requirements	• Ensure access to source data by authorized parties, and limit unauthorized access to protect confidentiality • Manage study records retention and availability after study conclusion