ACADEMY
OF CLINICAL RESEARCH PROFESSIONALS

Certified Principal Investigator (CPI®) Examination
Detailed Content Outline

(Effective 1 January 2017)

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 principal investigator. View Executive Summary for the most recent Job Analysis Study.

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Using the CPI Detailed Content Outline (DCO)

The CPI 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 CPI and therefore the content of the CPI Exam. To be certified, a PI 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	17%
II.	Ethical and Participant Safety Considerations	25%
III.	Product Development and Regulation	10%
IV.	Clinical Trial Operations (GCPs)	15%
V.	Study and Site Management	23%
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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As defined by the most recent ACRP Job Analysis Survey, a CPI® shall have proficient **knowledge** (middle column) in the following six (6) content areas of clinical research. A CPI typically uses this knowledge to perform the **tasks** listed (last column).

Content Area	CPIs must demonstrate proficient knowledge within the following areas:	CPIs typically perform the following tasks:
1. Scientific Concepts and Research Design (17%)	**1.1 elements of an Investigational Brochure (IB) and/or investigational device use (instructions for use)**	Review/Analyze background information (e.g., product development plan, IB)
		Identify the expected or unexpected results associated with investigational products
		Develop research question and/or hypothesis
		Identify the safety and expected therapeutic effects of the investigational product by verifying the preclinical and clinical research done so far (using the IB)
		Develop, update, and/or review the Investigators' Brochure
	1.2 elements of a protocol	Develop the protocol (e.g., inclusion/exclusion criteria, procedures, schedule of events, safety and efficacy parameters)
		Implement plan of action for management of adverse event(s) [e.g., stop investigational product, retest, treat subject]
		Identify and/or explain study objective(s) and endpoints
		Identify and/or explain study design
	1.3 rationale for complying with a protocol	Evaluate protocol for scientific soundness (e.g., risks, benefits, validity of study procedures, endpoints)
		Evaluate protocol for feasibility (in terms of practicality of execution, not evaluation by site)
		Ensure compliance with study requirements and regulations

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Content Area	CPIs must demonstrate proficient knowledge within the following areas:	CPIs typically perform the following tasks:
		Ensure consistency between the sites' standard operating procedures (SOPs) and the study requirements
	1.4 study objective(s) and end points/outcomes	Identify and/or explain study objective(s) and endpoints
		Critically analyze study results
		Prepare clinical trial/study report
	1.5 elements of and rationale for subject eligibility requirements	Develop and/or follow a recruitment strategy
		Conduct prescreening activities with potential study subjects
		Screen trial subjects
	1.6 statistical principles	Critically analyze study results
		Identify and/or explain study design
		Prepare clinical trial/study report
		Develop and/or maintain randomization procedures of investigational product
	1.7 study design characteristics (e.g., double-blind, crossover, randomized)	Identify and/or explain study design
		Conduct unblinding procedures as applicable
		Evaluate study for feasibility (site determining ability to successfully conduct the study)
		Develop and/or maintain randomization procedures of investigational product
		Develop and/or Maintain unblinding procedures of investigational product
	1.8 treatment assignments (e.g., randomization, open label, registries)	Develop and/or maintain randomization procedures of investigational product
		Ensure clinical trial registry requirements are met
		Minimize potential risks to subject safety

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Content Area	CPIs must demonstrate proficient knowledge within the following areas:	CPIs typically perform the following tasks:
	1.9 supplemental/rescue/comparator product(s) in study design	Assess subject safety during study participation
		Ensure and document follow-up medical care for study subjects, as applicable
		Assess, manage, and/or review subject laboratory values, test results, and alerts
2. Ethical and Participant Safety Considerations (25%)	**2.1 protection of human subjects**	Develop and/or review informed consent form
		Comply with subject privacy regulations
		Ensure adequate consent and documentation
		Verify adequate implementation and documentation of the informed consent process
		Implement plan of action for management of adverse event(s) [e.g., stop investigational product, retest, treat subject]
	2.2 vulnerable subject populations	Identify and/or address potential ethical issues involved with study conduct
		Minimize potential risks to subject safety
		Develop and/or implement study education plan and/or tools for subjects
		Participate in and document the informed consent process(es)
	2.3 subject safety issues	Assess, manage, and/or review subject laboratory values, test results, and alerts
		Differentiate the types of adverse events that occur
		Assess AE causality
		Maintain follow-up to determine resolution of adverse event(s)
		Ensure timely review of safety data
	2.4 confidentiality and privacy requirements	Comply with subject privacy regulations
		Ensure compliance with study requirements and regulations
		Prepare the study site for audits and inspections

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Content Area	CPIs must demonstrate proficient knowledge within the following areas:	CPIs typically perform the following tasks:
	2.5 conflicts of interest in clinical research	Comply with IRB/IEC requirements
		Identify the role and proper composition of IRB/IECs
		Ensure IRB/IEC review/written approval of study and study documents
		Ensure compliance with study requirements and regulations
	2.6 elements of the IB	Review/Analyze background information (e.g., product development plan, IB)
		Identify the expected or unexpected results associated with investigational products
		Develop research question and/or hypothesis
		Identify the safety and expected therapeutic effects of the investigational product by verifying the preclinical and clinical research done so far (using the IB)
		Develop, update, and/or review the Investigators' Brochure
	2.7 recruitment plan/strategies	Develop and/or follow a recruitment strategy
		Prepare and/or submit documents for IRB/IEC and/or sponsor review/approval
		Ensure IRB/IEC review/written approval of study and study documents
		Re-evaluate the recruitment strategy as needed
	2.8 elements of the informed consent form	Develop and/or review informed consent form
		Ensure adequate consent and documentation
		Instruct subjects on proper use of investigational product
		Implement protocol amendments
	2.9 informed consent process requirements	Verify adequate implementation and documentation of the informed consent process
		Delegate study-related roles and responsibilities

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Content Area	CPIs must demonstrate proficient knowledge within the following areas:	CPIs typically perform the following tasks:
		Escalate significant findings as appropriate
		Comply with IRB/IEC requirements
	2.10 components of subject eligibility requirements	Screen trial subjects
		Document reasons for subject discontinuation (i.e., causes, contact efforts)
		Ensure investigator/site protocol compliance
		Assess subject compliance
	2.11 blinding/unblinding procedures	Develop and/or Maintain unblinding procedures of investigational product
		Manage investigational product recall at the site and from study subjects
		Conduct unblinding procedures as applicable
	2.12 safety monitoring	Verify appropriate reporting and documentation of adverse event(s)
		Ensure timely review of safety data
		Assess subject safety during study participation
		Oversee the management of safety risks (e.g., clinical holds, product recalls)
	2.13 adverse events classification, documentation and reporting	Assess AE causality
		Maintain follow-up to determine resolution of adverse event(s)
		Verify appropriate reporting and documentation of adverse event(s)
	2.14 subject discontinuation criteria/procedures	Document reasons for subject discontinuation (i.e., causes, contact efforts)
		Ensure timely review of safety data
		Assess subject safety during study participation
	2.15 subject retention strategies	Develop and/or implement study education plan and/or tools for subjects
		Schedule subjects
		Conduct subject visits
		Develop trial management tools
	2.16 protocol deviation/violation identification, documentation, and	Identify and report potential fraud and misconduct

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Content Area	CPIs must demonstrate proficient knowledge within the following areas:	CPIs typically perform the following tasks:
	reporting processes	Investigate potential fraud and misconduct
		Develop or participate in protocol training
3. Product Development and Regulation (10%)	**3.1 clinical development process (e.g., preclinical, clinical trial phases, device class)**	Develop and/or review the product development plan
		Develop research question and/or hypothesis
		Review/Analyze background information (e.g., product development plan, IB)
		Identify the safety and expected therapeutic effects of the investigational product by verifying the preclinical and clinical research done so far (using the IB)
	3.2 IRB/IEC role, composition and purpose	Comply with IRB/IEC requirements
		Identify the role and proper composition of IRB/IECs
		Coordinate protocol and/or protocol amendments through appropriate approval processes (e.g., IRB/IEC, sponsor, regulatory authority)
	3.3 IRB/IEC reporting requirements	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
		Prepare study summary and/or close-out letter for IRB/IEC
	3.4 regulatory reporting requirements	Inform study subjects of trial results, in accordance with regulatory requirements
		Inform the sponsor and IRB/IEC of any deviations from the protocol and document as appropriate
		Ensure compliance with study requirements and regulations
		Submit documents to regulatory authorities
		Prepare for and/or participate in audits and inspections
		Respond to or facilitate response to

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Content Area	CPIs must demonstrate proficient knowledge within the following areas:	CPIs typically perform the following tasks:
		audit/inspection findings
	3.5 protocol and protocol amendment submission and approval processes	Prepare and/or submit documents for IRB/IEC and/or sponsor review/approval
		Ensure IRB/IEC review/written approval of study and study documents
		Submit documents to regulatory authorities
		Identify issues requiring protocol amendments
		Implement protocol amendments
	3.6 safety reporting requirements	Develop, update, and/or review the Investigators' Brochure
		Submit documents to regulatory authorities
		Verify appropriate reporting and documentation of adverse event(s)
	3.7 elements of fraud and misconduct	Identify and report potential fraud and misconduct
		Investigate potential fraud and misconduct
		Select qualified investigational staff
		Verify that investigational staff is qualified
	3.8 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
		Ensure appropriate staff, facility, and equipment availability throughout the study
	3.9 significant milestones in the evaluation of efficacy and safety (e.g., interim analysis result, DSMB review)	Ensure timely review of safety data
		Assess subject safety during study participation
		Ensure timely review of study data
4. Clinical Trial Operations	**4.1 roles of various clinical trial entities (e.g., CROs, sponsors, regulatory authority, vendors, etc.)**	Delegate study-related roles and responsibilities
		Develop project management tools

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Content Area	CPIs must demonstrate proficient knowledge within the following areas:	CPIs typically perform the following tasks:
(GCPs) (15%)		Obtain/verify vendor credentials (e.g., lab certification/licensure)
		Select qualified investigational staff
	4.2 project feasibility considerations	Schedule, coordinate, and/or participate in pre-study site visit
		Evaluate protocol for feasibility (in terms of practicality of execution, not evaluation by site)
		Evaluate study for feasibility (site determining ability to successfully conduct the study)
		Identify issues requiring protocol amendments
		Facilitate site budget/contract approval process
	4.3 principal investigator responsibilities	Verify that investigational staff is qualified
		Develop or participate in protocol training
		Prepare, conduct and/or participate in study initiation activities
		Plan, conduct and/or participate in training of the investigational staff
	4.4 indemnification/insurance requirements	Obtain/verify vendor credentials (e.g., lab certification/licensure)
		Facilitate site budget/contract approval process
		Evaluate and/or verify investigator indemnification/ insurance
	4.5 delegation of duties	Verify that investigational staff is qualified
		Delegate study-related roles and responsibilities
		Plan, conduct and/or participate in training of the investigational staff
		Ensure investigator/site protocol compliance
		Maintain study related logs (e.g., site signature

Content Area	CPIs must demonstrate proficient knowledge within the following areas:	CPIs typically perform the following tasks:
		log, screening log)
		Identify and/or maintain Essential Documents required for study conduct
	4.6 staff training requirements	Ensure appropriate staff, facility, and equipment availability throughout the study
		Select qualified investigational staff
		Delegate study-related roles and responsibilities
	4.7 site initiation activities	Verify Essential Documents required for study conduct
		Develop source document templates
		Develop and implement monitoring guidelines/plans
		Prepare, conduct and/or participate in study initiation activities
		Schedule, coordinate, and/or participate in pre-study site visit
	4.8 staff oversight	Prepare, conduct, and/or participate in interim monitoring visit(s)
		Perform onsite monitoring activities
		Create, document, and/or implement corrective and preventive action (CAPA) plans
	4.9 principles of study monitoring (e.g., risk-based, full SDV, remote, etc.)	Develop and implement monitoring guidelines/plans
		Prepare, conduct, and/or participate in interim monitoring visit(s)
		Perform onsite monitoring activities
		Document, communicate, and follow up on site visit findings
	4.10 elements of an effective corrective and preventive action (CAPA) plan	Document, communicate, and follow up on site visit findings
		Create, document, and/or implement

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Content Area	CPIs must demonstrate proficient knowledge within the following areas:	CPIs typically perform the following tasks:
		corrective and preventive action (CAPA) plans
		Escalate significant findings as appropriate
		Identify issues and recommend investigator/site corrective actions
	4.11 site close-out activities	Prepare for and participate in close-out monitoring visit(s)
		Reconcile investigational product and related supplies
		Ensure proper storage, dispensing, handling, and disposition of investigational product and related supplies
		Ensure proper collection, processing, and shipment of specimens (e.g., centrifuge, preparation of slides, freezing, refrigeration)
		Manage study records retention and availability
5. Study and Site Management (23%)	**5.1 roles of various clinical trial entities (e.g., CROs, sponsors, regulatory authority, vendors, etc.)**	Delegate study-related roles and responsibilities
		Develop project management tools
		Obtain/verify vendor credentials (e.g., lab certification/licensure)
		Select qualified investigational staff
	5.2 elements of a study budget	Facilitate site budget/contract approval process
		Develop trial management tools
		Evaluate study for feasibility (site determining ability to successfully conduct the study)
	5.3 contract budget negotiations and approval process	Facilitate site budget/contract approval process
		Evaluate and/or verify investigator indemnification/ insurance
		Coordinate protocol and/or protocol amendments through appropriate approval processes (e.g., IRB/IEC, sponsor, regulatory

Content Area	CPIs must demonstrate proficient knowledge within the following areas:	CPIs typically perform the following tasks:
		authority)
	5.4 project and/or study timelines	Manage study supplies (e.g., lab kits, case report forms)
		Ensure adequacy of investigational product and other supplies at site
		Monitor investigational product expiration and/or manage resupply
		Develop project management tools
		Develop trial management tools
		Schedule subjects
	5.5 investigational product characteristics (e.g., mechanism of action, stability, etc.)	Prepare investigational product for administration
		Dispense investigational product
		Reconcile investigational product and related supplies
		Maintain accountability of investigational product
		Monitor investigational product expiration and/or manage resupply
	5.6 investigational product reference materials (e.g., Investigational Brochure, instructions for use, user manual)	Ensure proper storage, dispensing, handling, and disposition of investigational product and related supplies
		Prepare investigational product for administration
		Dispense investigational product
	5.7 investigational product storage	Ensure proper storage, dispensing, handling, and disposition of investigational product and related supplies
		Ensure adequacy of investigational product and other supplies at site
		Monitor investigational product expiration and/or manage resupply
		Maintain accountability of investigational product
	5.8 investigational product	Reconcile investigational product and related

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Content Area	CPIs must demonstrate proficient knowledge within the following areas:	CPIs typically perform the following tasks:
	accountability and documentation requirements	supplies
		Maintain accountability of investigational product
		Ensure proper storage, dispensing, handling, and disposition of investigational product and related supplies
	5.9 equipment and supplies use and maintenance	Obtain/verify vendor credentials (e.g., lab certification/licensure)
		Manage study supplies (e.g., lab kits, case report forms)
		Perform and/or verify equipment calibration and maintenance
	5.10 sample collection, shipment, and storage requirements	Ensure proper collection, processing, and shipment of specimens (e.g., centrifuge, preparation of slides, freezing, refrigeration)
		Follow standards for handling hazardous goods (e.g., International Air Transport Association (IATA)
		Manage study supplies (e.g., lab kits, case report forms)
	5.11 subject responsibilities for study participation	Instruct subjects on proper use of investigational product
		Assess subject compliance
		Ensure adequate consent and documentation
	5.12 subject visit activities	Conduct prescreening activities with potential study subjects
		Assess subject compliance
		Conduct subject visits
	5.13 subject compliance assessment	Assess subject compliance
		Reconcile investigational product and related supplies
		Ensure investigator/site protocol compliance
	5.14 communication documentation requirements (e.g., telephone, email, etc.)	Develop source document templates
		Document, communicate, and follow up on site visit findings

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Content Area	CPIs must demonstrate proficient knowledge within the following areas:	CPIs typically perform the following tasks:
		Develop trial management tools
	5.15 purpose of and process(es) for protocol compliance	Ensure investigator/site protocol compliance
		Plan, conduct and/or participate in training of the investigational staff
		Develop trial management tools
	5.16 corrective and preventive action (CAPA) process(es) and plan	Create, document, and/or implement corrective and preventive action (CAPA) plans
		Escalate significant findings as appropriate
		Identify issues and recommend investigator/site corrective actions
	5.17 investigational product shipment	Maintain accountability of investigational product
		Manage investigational product recall at the site and from study subjects
		Monitor investigational product expiration and/or manage resupply
		Verify Essential Documents required for study conduct
6. Data Management and Informatics (10%)	**6.1 essential documents for the conduct of a clinical trial (e.g., trial master file)**	Identify and/or maintain Essential Documents required for study conduct
		Verify Essential Documents required for study conduct
		Manage study records retention and availability
	6.2 elements and purposes of data collection tools (e.g., eCRF, EDC)	Review and approve completed eCRF/CRF
		Collect, record, and report accurate and verifiable data
		Transmit data to Data Management
	6.3 source documentation requirements	Develop source document templates
		Collect, record, and report accurate and verifiable data
		Perform query resolution
	6.4 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

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Content Area	CPIs must demonstrate proficient knowledge within the following areas:	CPIs typically perform the following tasks:
		Ensure consistency between the sites' standard operating procedures (SOPs) and the study requirements
		Comply with subject privacy regulations
	6.5 study documentation practices (accurate, complete, timely, legible, dated, and identify the trial)	Collect, record, and report accurate and verifiable data
		Perform query resolution
		Manage study records retention and availability
	6.6 source data review (SDR) and source data verification (SDV) purpose and process	Perform query resolution
		Ensure access to source data by authorized parties, and protect confidentiality by limiting unauthorized access
		Perform onsite monitoring activities
		Document, communicate, and follow up on site visit findings
	6.7 data management principles	Develop trial management tools
		Collect, record, and report accurate and verifiable data
		Transmit data to Data Management
		Ensure timely review of study data
		Ensure compliance with electronic data requirements (e.g., passwords and access)
	6.8 record retention and destruction practices and requirements	Ensure access to source data by authorized parties, and protect confidentiality by limiting unauthorized access
		Manage study records retention and availability
		Ensure timely review of study data
		Maintain study related logs (e.g., site signature log, screening log)