ACADEMY
OF CLINICAL RESEARCH PROFESSIONALS

Association of Clinical Research Professionals – Project Management (ACRP-PM®) Designation Subspecialty Examination Detailed Content Outline

(Effective June 1, 2018)

Introduction

In following best practices, the Academy conducted a Job Analysis Study to ensure content validity of the ACRP-PM 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 survey data specifications to assess clinical research project management professionals' competence, and determine the level of importance of specific knowledge and tasks required to perform in the role of an ACRP-PM. This document contains the Detailed Content Outline (DCO) for the ACRP-PM. Each question on the exam is based on this outline.

Using the ACRP-PM Detailed Content Outline (DCO)

The results of the study provided the framework for the knowledge and tasks important to the role of an ACRP- PM and therefore the content of the exam. To earn the ACRP-PM designation subspecialty, it 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		Items on Exam
I.	Ethical and Participant Safety Considerations	10%
II.	Regulatory Requirements	10%
III.	Clinical Trial Operations (GCPs)	25%
IV.	Study Management	30%
V.	Scientific Concepts and Research Design	10%
VI.	Business Management, Leadership, and Professionalism	15%
	Total	**100%**

The specific knowledge and tasks identified as important are provided in the Project Management DCO listed below. Therefore, to prepare to take the ACRP-PM Exam, one should study this outline and especially consider the underlying knowledge, skills, and abilities needed. It is recommended that an eligible candidate use this outline to identify knowledge gaps for constructing a relevant preparation plan.

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Content Area I	**Ethical and Participant Safety Considerations – 10%**
Task 1	Develop and/or review informed consent form.
Task 2	Oversee compliance with the requirements for human subject protections and privacy under different national and international regulations and ensure their implementation throughout all phases of a clinical study.
Task 3	Collect and/review information about potential conflicts of interest.
	Knowledge: • Human Subject protections and privacy oversight and compliance • Informed consent form development and review • Recruitment plan/strategy • Safety monitoring • Subject retention strategies • Conflicts of interest in clinical research
Content Area II	**Regulatory Affairs – 10%**
Task 1	Oversee compliance with the regulatory requirements that are applicable for investigational product/device development and/or research protocol.
Task 2	Manage budgetary and logistical aspects of investigational product/device accountability

	• Knowledge: • The roles and responsibility of the various stakeholders and regulatory institutions in the clinical trials • Regulatory reporting requirements (e.g. pre- and post-approval, safety, grant submission) • Audit and inspection processes (preparation, participation, documentation, and follow -up) • Clinical trial registries and requirements • Fraud and misconduct identification, reporting, and management • Significant milestones in the evaluation of efficacy and safety (e.g., interim analysis result, DSMB/IDMC review)
Content Area III	**Clinical Trial Operations – 25%**
Task 1	Evaluate the conduct and management of clinical trials within the context of applicable plans (e.g., protocol, study plan, monitoring plan, data management plan).
Task 2	Participate in audits and inspections (e.g. prepare, support, respond).
Task 3	Coordinate and oversee protocol, protocol amendments, and other relevant documents through appropriate approval processes (e.g., IRB/IEC, sponsor, regulatory authority).
Task 4	Develop or participate in protocol and study training (e.g., site initiation visit, investigator meeting, webinar).
Task 5	Identify issues potentially requiring protocol amendments.
Task 6	Develop and/or utilize study management tools.
Task 7	Create, document, and/or implement corrective and preventive action (CAPA).
Task 8	Integrate a risk-based approach to quality management (e.g. risk assessment).
Task 9	Escalate significant issues as appropriate.
Task 10	Prepare, support and/or participate in close-out activities (site or study).
Task 11	Oversee vendors (e.g., labs, IRB/IEC, technology, subject recruitment, CRO).
Task 12	Oversee the collection, maintenance, verification, and/or storage of regulatory essential documents.
Task 13	Manage investigational product/device recall process.
Task 14	Oversee and approve initial shipment of investigational product to site.

	Knowledge • Conduct and management of clinical trials within the context of applicable plans (e.g. protocol, study plan, monitoring plan, data management plan). • Roles and responsibilities of the clinical investigation team as defined by GCP. • Protocol required control, storage, and dispensation of investigational products/devices. • Reporting requirements relating to clinical trial conduct (e.g., SAEs, deviations, INDs, IRB/IEC). • The processes and purposes for monitoring of the study. • Identification, management, and reporting requirements for protocol/GCP deviation/violation. • IRB/IEC requirements such as submission, review, and approval of documents. • Collecting, tracking, and monitoring of the delegation of responsibilities. • Elements and development of an effective corrective and preventive action? (CAPA) • Requirements of indemnification/insurance • Site selection activities. • Project feasibility considerations. • Study and site initiation maintenance, and close-out activities (e.g., vendor oversight, quality management).
Content Area IV	**Study Management – 30%**
Task 1	Develop and/or manage resources necessary to conduct a study (e.g., the financial, timeline, and cross-disciplinary personnel.
Task 2	Oversee quality control activities in the conduct of clinical research.
Task 3	Continually evaluate subject recruitment strategy and study programs.
Task 4	Manage staff to performance metrics.
Task 5	Develop, review, and/or implement study plans and/or tools (e.g., subject materials, recruitment plan, lab manuals).
Task 6	Manage the protocol amendments process.
Task 7	Obtain and/or confirm presence of a signed indemnification/insurance, contracts, and/or budgets.
Task 8	Assess protocol compliance (visits, procedures, reporting).

Task 9	Manage and/or review investigative product/device expiration and/or manage resupply or relabeling.
Task 10	Oversee and manage the study contract process.
Task 11	Develop and/or negotiate study budget.
	Knowledge: • Quality management activities in the conduct of clinical research. • Resources necessary to conduct a study (e.g., financial, timeline, and cross-disciplinary personnel, personnel qualifications, job requirements). • Methods used to track subject recruitment and study progress. • Coordination of the various entities involved in the conduct of a clinical trial (e.g., legal, liabilities, accountabilities). • Procedures, documentation, and oversight requirements of PIs, sponsors, contract research organizations (CROs), and regulatory authorities. • Contractual agreements (e.g., budgets, clinical trial agreement, indemnification/insurance). • Investigational product/device oversight (e.g., supply, labeling, distribution, disposition, reference materials, expiration dates). • Vendor management (e.g., labs, IRB/IEC, technology, subject recruitment, CRO). • Billing compliance process (e.g., standard of care versus protocol-specific billing).
Content Area V	**Scientific Concepts and Research Design – 10%**
Task 1	Review the protocol and supporting documentation (e.g., investigators brochure, instructions for use, package insert).
Task 2	Identify and/or describe study design.
Task 3	Identify and/or describe study hypothesis for investigator-initiated trials.
	Knowledge: • Risk management strategies and principles (e.g., quality management systems, scientific validity). • Components of a product development plan (e.g., timelines, General Investigational Plan)
Content Area VI	**Business Management, Leadership, and Professionalism – 15%**
Task 1	Apply the principles and practices of leadership, management, and mentorship within the working environment

Task 2	Lead culturally diverse teams
	Knowledge: • Principles and practices of leadership, management, and mentorship, and how to apply them within the working environment. • Difference in cultural norms and practices. • Staff performance metrics • Management concepts and effective training methods to manage risk and improve quality in conduct of a clinical research study. • Budget and resource management. • Financial management and reporting.