ACRP ACADEMY OF CLINICAL RESEARCH PROFESSIONALS

2024 EXAMINATION CONTENT OUTLINE:

ACRP-PM® SPECIALTY

The Exam Content Outline (ECO) serves as a foundational guide for candidates preparing for the ACRP Project Manager (ACRP-PM®) exam. It delineates the essential domains, knowledge statements, and tasks that are critical for performing effectively in the certified role.

STRUCTURE

The ECO is structured into three main components:

1. **Domains:** Broad areas of knowledge and skills necessary for the role.
2. **Knowledge Statements:** Specific pieces of knowledge that a certified professional should possess within each domain.
3. **Tasks:** Practical tasks that a professional in the role should be able to perform, demonstrating the application of their knowledge.

EXAM PREPARATION

Candidates can utilize the ECO as a strategic tool in their exam preparation. By thoroughly understanding each domain, knowledge statement, and task, candidates can identify their strengths and areas needing improvement. This targeted approach to study can enhance readiness and confidence for the ACRP-PM® exam.

DEVELOPMENT

The ECO is developed through a comprehensive role delineation study, also known as a job analysis. This process ensures that the ECO stays relevant and aligns with current industry standards and practices. The development is led by a dedicated group of certified subject matter experts with extensive experience in the role. Their insights and expertise are crucial in identifying and validating the key competencies required for certification.

For more details on the Project Manager specialty please visit the ACRP website.

DOMAIN I	ETHICAL AND PARTICIPANT SAFETY CONSIDERATIONS – 25%
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 Statements • 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
DOMAIN 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 Statements • 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)
DOMAIN 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 Statements • 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).
DOMAIN 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 Statements • 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).
DOMAIN 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 Statements • Risk management strategies and principles (e.g., quality management systems, scientific validity). • Components of a product development plan (e.g., timelines, General Investigational Plan)

DOMAIN 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 Statements • 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.