ACRP ACADEMY OF CLINICAL RESEARCH PROFESSIONALS

2024 EXAMINATION CONTENT OUTLINE:

ACRP-MDP® SPECIALTY

The Exam Content Outline (ECO) serves as a foundational guide for candidates preparing for the ACRP Medical Device Professional (ACRP-MDP®) 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-MDP® 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 Medical Device Professional specialty please visit the ACRP website.

DOMAIN I	ETHICAL AND PARTICIPANT SAFETY CONSIDERATIONS – 25%
Task 1	Review the safety and performance of the investigational product/device (e.g., using the instructions for use/IB)
Task 2	Develop the informed consent form, and process for obtaining consent
Task 3	Compare and contrast clinical care and clinical management of research participants (e.g., standard of care vs protocol requirements)
Task 4	Identify and comply 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 5	Identify safety risks related to device studies
Task 6	Confirm the inclusion and exclusion criteria assure human subject protection
Task 7	Evaluate and/or explain the benefits versus risks for study subject protection
Task 8	Develop, maintain, and/or review unblinding procedures as applicable
Task 9	Evaluate potential conflicts of interest
Task 10	Manage device recalls, study holds, and safety alerts
Task 11	Manage subject registries and long-term follow-up, continued access
	Knowledge Statements • the requirements for human subject protections and privacy • the principles and methods of risk versus benefit through selection and management of clinical trial subjects • adverse event, device effect, and device deficiencies classification, documentation, and reporting • blinding procedures • components of subject eligibility requirements (e.g., eligibility deviations and subject follow-up, anatomical assessment) • elements of the instructions for use/IB • safety monitoring • subject discontinuation criteria/procedures • subject registries, long-term follow-up, and continued access strategies • subject safety and privacy issue management • conflicts of interest in clinical research • device recalls, study holds, and safety alerts
DOMAIN II	**INVESTIGATIONAL PRODUCT/DEVICE REGULATION – 10%**
	Knowledge Statements • the roles and responsibilities of the various stakeholders in the clinical trials (e.g., field clinical engineer, sponsor representative) • the specific processes and phases that must be followed for an investigational product/device (e.g., feasibility, pilot, pivotal, post market) • regulatory reporting requirements (e.g., pre- and post-approval, safety) • clinical trial registries and requirements (e.g., post market clinical follow-up)

DOMAIN III	CLINICAL TRIAL OPERATIONS (GCPS) – 30%
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	Review and/or document the process of appropriate control, storage, shipment, and dispensing of investigational products
Task 3	Differentiate the types of adverse event, device effect, and device deficiencies that can occur during clinical trials, and their identification and reporting process
Task 4	Comply with the safety reporting requirements of regulatory agencies both pre- and post-approval
Task 5	Assess compliance and documentation of consent process
Task 6	Verify continuity of medical care is provided for study subjects
Task 7	Identify and/or manage adverse event, adverse device affects, and device deficiencies (e.g., treat subject, adjust treatment based on subject need and protocol)
Task 8	Assess qualifications of the investigational site, site staff, and principal investigator
Task 9	Develop or participate in protocol training
Task 10	Develop or participate in investigational product/device training
Task 11	Identify issues potentially requiring protocol amendments
Task 12	Develop, update, and/or review the instructions for use/IB
Task 13	Develop and/or utilize study device assessment tools (e.g., pacemaker interrogator)
Task 14	Assess investigator/site/subject protocol compliance
Task 15	Conduct initial risk assessment and ongoing risk assessment review
Task 16	Oversee vendors (e.g., core labs, IRB/IEC, technology, subject recruitment, CRO)
Task 17	Collect, maintain, verify, and/or store regulatory essential documents
Task 18	Comply with randomization procedures of investigational product/device
Task 19	Manage investigational product/device recall
Task 20	Identify critical elements of an investigator agreement

	Knowledge Statements • protocol required control, storage, shipment, and dispensation of investigational products/devices • adverse event, device effect, and device deficiencies that occur during clinical trials, and the identification process • IRB/IEC requirements such as submission, review, and approval of documents (e.g., significant risk determination) • delegation of responsibilities • purpose and use of the instructions for use/IB • requirements of indemnification/insurance • site selection activities • principal investigator responsibilities • project feasibility considerations • site initiation activities
DOMAIN IV	**STUDY AND SITE MANAGEMENT – 30%**
Task 1	Develop and/or manage resources necessary to conduct a study (the financial, timeline, and cross-disciplinary personnel)
Task 2	Participate in and document the informed consent process(es)
Task 3	Develop, review, and/or implement study plans and/or tools (e.g., subject materials, recruitment plan, lab manuals)
Task 4	Evaluate reasons for subject discontinuation (e.g., causes, contact efforts)
Task 5	Evaluate study for feasibility (e.g., site determining ability to successfully conduct the study)
Task 6	Obtain and/or confirm presence of a signed indemnification/insurance, contracts, and/or budgets
Task 7	Assess protocol compliance (visits, procedures, reporting)
Task 8	Instruct subjects on protocol requirements and assess compliance (e.g., investigational product/device, diaries/logs, visits)
Task 9	Perform and/or verify study device and diagnostic equipment calibration and maintenance
Task 10	Verify appropriate staff, facility, supplies, and equipment availability throughout the study
Task 11	Manage and/or review investigational product/device expiration and/or manage resupply or relabeling
Task 12	Oversee device returns (e.g., unused returns, recalls, explant)
Task 13	Manage device deficiency reporting
Task 14	Record, and/or review data for accuracy and verifiability (e.g., device data transmitted directly, data collection devices)

	Knowledge Statements • resources necessary/ feasibility to conduct a study (e.g., financial, timeline, and cross-disciplinary personnel) • how to assess, manage, and/or report adverse event, device effect, and device deficiencies causality, severity, and relationship to investigational product/device • maintenance and use of equipment and supplies • investigational product/device accountability and documentation requirements • investigational product/device use (e.g., training, expected side effects, device modification or alterations) • investigational product/device reference materials (e.g., instructions for use/IB, user manual) • investigational product/device receipt, storage, disposition, returns, and shipment requirements • how to assess subject compliance • subject responsibilities for study participation • vendor management (e.g., labs, IRB/IEC, technology, subject recruitment, CRO) • principal investigator oversight requirements • subject discontinuation process • adverse event, device effect, and device deficiencies oversite (e.g., data safety monitoring board (DSMB), clinical events committee (CEC)
DOMAIN V	**SCIENTIFIC CONCEPTS AND RESEARCH DESIGN – 5%**
Task 1	Evaluate protocol for practicality of execution
Task 2	Identify and/or implement risk management strategies (e.g., subject, investigational product/device, data handling)
Task 3	Identify and/or describe study design
	Knowledge Statements • elements of an investigational device use (Instructions for Use) and/or Investigational Brochure (IB) • risk management strategies and principles (e.g., quality management systems)