ACADEMY
OF CLINICAL RESEARCH PROFESSIONALS

Medical Device Professional (ACRP-MDP®)
Designation Subspecialty Examination
Detailed Content Outline

(Effective May 1, 2019)

Introduction

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

Using the ACRP-MDP Detailed Content Outline (DCO)

The results of the study provided the framework for the knowledge and tasks important to the role of an ACRP-MDP and therefore the content of the exam. To become certified, it is expected to have proficiency in the five (5) 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	25%
II.	Investigational Product/Device Regulations	10%
III.	Clinical Trial Operations (GCPs)	30%
IV.	Study and Site Management	30%
V.	Scientific Concepts and Research Design	5%
	Total	**100%**

The specific knowledge and tasks identified as important are provided in the Medical Device Professional DCO listed below. Therefore, to prepare to take the ACRP-MDP 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 – 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	• 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

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Content Area II	Investigational Product/Device Regulation – 10%
Knowledge	• 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)
Content Area 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	• 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
Content Area 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	• 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)
Content Area 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	• elements of an investigational device use (Instructions for Use) and/or Investigational Brochure (IB) • risk management strategies and principles (e.g., quality management systems)