ACRP ACADEMY OF CLINICAL RESEARCH PROFESSIONALS

2024 EXAMINATION CONTENT OUTLINE:

CPI® CERTIFICATION

The Exam Content Outline (ECO) serves as a foundational guide for candidates preparing for the ACRP Certified Principal Investigator (CPI®) 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 CPI® certification exam.

DEVELOPMENT

ACRP develops the ECO every five years 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 Certified Principal Investigator certification, please visit the ACRP website.

EXAMINATION CONTENT OUTLINE

1	**Scientific Rationale and Principles of Research Design**	**15**
1A	Objectives and processes including statistical principles and study end points	
1B	Design, investigational products/devices, and treatment assignments	
2	**Ethical and Safety Considerations**	**22**
2A	Human participant protection	
2B	Safety monitoring/reporting	
3	**Product Development and Regulation**	**12**
3A	Product development cycle	
3B	IRB/IEC/Regulatory function and reporting	
3C	Data monitoring and inspection	
4	**Clinical Trial Operations**	**21**
4A	Feasibility and study conduct	
4B	Investigator responsibilities	
4C	Quality assurance	
5	**Study and Site Management**	**17**
5A	Investigational product management	
5B	Equipment and supplies	
5C	Clinical trial/site management	
5D	Operational participant oversight	
6	**Data Management**	**13**
6A	Clinical trial documentation	
6B	Protected health information/Data confidentiality	
6C	Data review and retention	

TASK STATEMENTS

1. Address participant laboratory values, test results, and alerts
2. Analyze and/or explain study results
3. Approve site budget/contract
4. Assess participant safety
5. Collect, record, and report accurate and verifiable data
6. Comply with electronic data requirements

7. Comply with participant privacy regulations
8. Comply with randomization and blinding/unblinding procedures for investigational product
9. Comply with regulatory requirements
10. Comply with study requirements and regulations
11. Conduct prescreening activities with potential study participants
12. Create, document, and/or implement corrective and preventive action (CAPA) plans
13. Delegate study-related roles and responsibilities as appropriate
14. Develop and participate in protocol training
15. Identify the various components of a protocol
16. Develop, modify, and/or review informed consent form
17. Develop, update, and/or review the Investigators' Brochure
18. Document reasons for participant discontinuation
19. Educate participant on proper use of investigational product
20. Engage in and respond to audits and inspections
21. Engage in study initiation, monitor visits, and close-out activities
22. Ensure access to source data by authorized parties
23. Ensure and document follow-up medical care for study participants, as applicable
24. Ensure and document training of the investigational staff
25. Ensure appropriate staff, facility, supplies, and equipment
26. Ensure comprehensive source documentation
27. Ensure ongoing informed consent and documentation
28. Ensure protocol compliance
29. Ensure regulatory approval of study and study documents
30. Ensure timely review of study and safety data
31. Evaluate need to modify/terminate study based on efficacy, safety, or logistical concerns
32. Evaluate protocol for feasibility
33. Evaluate site for study feasibility
34. Explain and implement study design
35. Follow standards for handling hazardous materials
36. Identify and address potential ethical issues including fraud and misconduct
37. Identify issues requiring protocol amendments
38. Identify site issues and implement corrective actions
39. Identify the role and proper composition of regulatory bodies
40. Implement protocol amendments after appropriate approval
41. Implement quality management system
42. Inform study participants of trial risks, modifications, and results, in accordance with regulatory requirements
43. Limit unauthorized access to participant data to protect confidentiality
44. Maintain Essential Documents required for study conduct
45. Maintain ethical recruitment and retention strategies

46. Maintain investigational product
47. Maintain study records and retention
48. Manage protocol modifications through approval processes
49. Manage study education plan and tools for participants
50. Prepare and submit required documents for regulatory approval
51. Review and approve completed eCRF/CRF
52. Review and manage AEs, SAEs, adverse events of special interest, and adverse drug reactions
53. Schedule/perform/oversee participant visits
54. Screen trial participants
55. Select qualified investigational staff
56. Timely inform the sponsor and regulatory body of any protocol deviations
57. Timely manage query resolutions
58. Verify compatibility of site SOPs with study requirements
59. Verify participant compliance
60. Verify vendor qualification