ACRP ACADEMY OF CLINICAL RESEARCH PROFESSIONALS

2024 EXAMINATION CONTENT OUTLINE:

CCRA® CERTIFICATION

The Exam Content Outline (ECO) serves as a foundational guide for candidates preparing for the ACRP Certified Clinical Research Associate (CCRA®) 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 CCRA® 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 Clinical Research Associate certification, please visit the ACRP website.

EXAMINATION CONTENT OUTLINE

1	**Scientific Concepts and Research Design**	**12**
1A	Elements of a protocol	
1B	Elements of an Investigational Brochure (IB) and/or investigational device use (instructions for use)	
1C	Rationale for participant eligibility requirements	
1D	Rationale for trial design	
1E	Study design characteristics (e.g., double-blind, crossover, randomized))	
1F	Study objective(s) and end points/outcomes	
1G	Use of comparator or control product in study design	
1H	Treatment assignments (e.g., randomization, open label, registries)	
1I	Stages of product development	
2	**Ethical and Participant Safety Considerations**	**18**
2A	Adverse events definitions/classification, documentation, and reporting (e.g., SAE, AESI, SUSAR)	
2B	Blinding/unblinding procedures	
2C	Elements of eligibility required by IRB/IEC	
2D	Confidentiality and privacy requirements	
2E	Risks and benefits of the safety profile	
2F	Elements of the informed consent	
2G	Informed consent process requirements	
2H	Protection of human subjects (e.g., IRB/IEC requirements, Declaration of Helsinki, participant compensation)	
2I	Protocol deviation/violation identification, documentation, and reporting processes	
2J	Recruitment and retention plan/strategies	
2K	Safety monitoring	
2L	Participant discontinuation criteria/procedures	
2M	Vulnerable participant populations	
2N	Conflicts of interest in clinical research (e.g., financial for PI or staff, family and site participation in trial)	
2O	Elements of potential fraud and misconduct	
3	**Regulatory Requirements**	**14**
3A	IRB/IEC reporting requirements and communication	
3B	IRB/IEC purpose, role, and composition	
3C	Protocol and protocol amendment submission and approval processes	
3D	Regulatory authority reporting requirements and communication (e.g., safety, CSR)	

4	**Clinical Trial Operations (GCP)**	**18**
4A	Elements of an effective root cause analysis and corrective and preventive action (CAPA) plan	
4B	Elements of and rationale for monitoring plan(s)	
4C	Monitoring responsibilities (e.g., purpose, extent, procedures)	
4D	Principal investigator responsibilities	
4E	Principles of risk-based monitoring/data governance	
4F	Project feasibility considerations	
4G	Responsibilities of various clinical trial entities/personnel (e.g., CROs, sponsors, regulatory authority, data manager)	
4H	Audits and inspection processes (preparation, participation, documentation, and follow-up)	
4I	Pre-study and site selection activities	
5	**Study and Site Management Activities**	**25**
5A	Communication documentation requirements (e.g., phone, email)	
5B	Equipment and supplies use and maintenance	
5C	Investigational product/device management (e.g., accountability, dispensing shipment, storage, labeling, and documentation requirements)	
5D	Processes and management of non-compliance (e.g., IRB, GCP, CFR, protocol)	
5E	Roles of various clinical trial entities/plan (e.g., medical monitor, vendors, IRB/IEC, sponsor, CRO)	
5F	Sample/diagnostic collection, shipment, verification, reporting, and storage requirements (e.g., lab, imaging, raters)	
5G	Participant compliance and responsibilities for study participation	
5H	Contracts and budgets (e.g., participant compensation, site payments)	
5I	Management of study site documentation (e.g., ISF/TMF reconciliation)	
5J	Delegation, qualification, and training of appropriate responsibilities at site	
5K	Site initiation activities	
5L	Interim visit activities	
5M	Site close-out activities	
5N	Essential document requirements (e.g., Trial Master File, Investigator Site File)	

6	**Data Quality**	**13**
6A	Data privacy principles and access to site/participant records (e.g., paper vs. EMR)	
6B	Elements and purposes of data collection tools (e.g., CRF/eCRF, patient reported outcome devices)	
6C	Elements of and process for data query (e.g., query writing)	
6D	Purpose of pharmacovigilance (e.g., CIOMS, IDMC/DSMB, safety databases)	
6E	Record retention and destruction practices and requirements	
6F	Source data review (SDR) and source data verification (SDV) purpose and process	
6G	Source documentation requirements and GDP (e.g., ALCOA+)	
6H	Critical variables and critical processes	
6I	Impact of efficacy and safety (e.g., interim analysis result, DSMB review)	

TASK STATEMENTS

1. Review background information and rationale (e.g. product development plan, IB, therapeutic area, history)
2. Explain standard of care versus research
3. Explain protocol elements (e.g. study design, objectives and endpoints, rationale, blinding, randomization)
4. Verify site's compliance with IRB/IEC requirements and other ethical considerations (e.g. Declaration of Helsinki, Belmont Report)
5. Develop and/or follow-up on recruitment strategy that complies with ethical considerations
6. Recognize and protect participant confidential information and comply with privacy regulations (e.g. HIPAA, GDPR)
7. Develop and/or review informed consent
8. Verify adequate implementation and documentation of the informed consent process
9. Verify subject eligibility meets protocol inclusion/exclusion criteria at enrollment and during study conduct
10. Develop and/or implement study education plan and/or tools for sites
11. Verify Investigator assessment and management of participant laboratory values, test results, and alerts
12. Identify and/or verify appropriate reporting and documentation of adverse events(s) to resolution
13. Verify timely review and submission of drug safety data by site

14. Verify the site's management of safety risks (e.g. clinical holds, product recalls, DSMB/IDMC documentation)
15. Verify adequate documentation of participant discontinuation (e.g. causes, contact efforts)
16. Identify and report potential fraud and misconduct
17. Verify that the documentation related to the IRB/IEC is present (e.g., composition, federal assurance number)
18. Prepare and/or submit documents for IRB/IEC review/approval
19. Inform the sponsor and confirm IRB/IEC submission of any deviations from the protocol and document as appropriate
20. Prepare for and/or participate in audits and inspections
21. Respond to or facilitate response to audit/inspection findings
22. Verify that investigational staff is qualified (e.g. CV, medical license, GCP qualifications, FDA debarment) per protocol
23. Prepare, conduct and/or participate in pre-study, site initiation, on-site monitoring, remote monitoring, close out, and co- monitoring/training visit(s)
24. Verify source documentation adheres to ALCOA+ principles
25. Document, communicate, and follow up on site visit activities and/or findings
26. Facilitate communication between site and sponsor
27. Evaluate trial sites for participation
28. Coordinate access to study systems (e.g. vendor portals, IVRS) and verify compliance with electronic data requirements
29. Facilitate and verify certification of translation of study documents
30. Manage study supplies (e.g. lab kits, study related devices)
31. Verify documentation of ongoing equipment calibration and maintenance
32. Confirm proper collection, processing, and shipment of specimens (e.g. centrifuge, preparation of slides, freezing, refrigeration)
33. Confirm proper storage, dispensing, handling, reconciliation and disposition of investigational product/device and associated supplies
34. Evaluate data collection tools (e.g. source worksheets, diaries and other collection devices) for consistency with protocol
35. Confirm transmission of data
36. Identify type of and location of source documentation
37. Conduct source data review (SDR) and/or source data verification (SDV)
38. Facilitate Investigator CRF/eCRF signatures and database lock
39. Review data for trends (e.g. central monitoring, data listing review, timeliness)