ACRP ACADEMY OF CLINICAL RESEARCH PROFESSIONALS

2024 EXAMINATION CONTENT OUTLINE:

CCRC® CERTIFICATION

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

EXAMINATION CONTENT OUTLINE

1	**Scientific Concepts and Research Design**	**8**
1A	Elements of a protocol	
1B	Elements of an Investigational Brochure (IB) and/or investigational device use	
1C	Elements of and rationale for subject eligibility requirements	
1D	Rationale for complying with a protocol	
1E	Statistical principles related to study design (e.g., sample size, screen fail rate)	
1F	Study design characteristics (e.g., double-blind, crossover, randomized)	
1G	Study objective(s)	
1H	Study endpoints/outcomes	
1I	Rationale for using supplemental/rescue/comparator product in study design	
1J	Treatment assignments (e.g., randomization, open label, registries)	
2	**Ethical and Participant Safety Considerations**	**19**
2A	Adverse events classification, documentation and reporting	
2B	Blinding/unblinding procedures	
2C	Components of subject eligibility requirements	
2D	Confidentiality and privacy requirements	
2E	Elements of the IB related to identifying risks and benefits	
2F	Elements of the informed consent form	
2G	Informed consent process requirements (e.g., paper, eConsent, assent)	
2H	Protection of human subjects including vulnerable subject populations	
2I	Protocol deviation/violation identification, documentation, and reporting processes	
2J	Subject recruitment and retention plan/strategies (e.g., social media, digital, print)	
2K	Safety monitoring and elements of pharmacovigilance and/or product/device vigilance (e.g., CIOMS, IDMC/DSMB, safety databases)	
2L	Subject discontinuation criteria/procedures	
2M	Subject safety	
2N	Conflicts of interest in clinical research	
2O	Ethical responsibilities including fraud and misconduct	

3	**Product Development and Regulation**	**13**
3A	Audit and inspection processes (preparation, participation, documentation, and follow-up)	
3B	Clinical development process (e.g., preclinical, clinical trial phases, device class)	
3C	Clinical trial registries and requirements	
3D	Elements of fraud and misconduct	
3E	IRB/IEC and other regulatory body reporting requirements	
3F	IRB/IEC role, composition, and purpose	
3G	Protocol and protocol amendment submission and approval processes	
3H	Safety reporting requirements	
3I	Significant milestones in the evaluation of efficacy and safety (e.g., interim analysis result, DSMB review)	
4	**Clinical Trial Operations (GCPs)**	**23**
4A	Site staff qualifications for delegation of responsibilities, duties, and training requirements	
4B	Elements of effective corrective and preventive action (CAPA) process(es) and plan(s)	
4C	Monitoring activities (frequency of visits, data review, and follow-up)	
4D	Pre-study/site selection criteria and visit activities	
4E	Principal investigator oversight responsibilities	
4F	Project feasibility considerations	
4G	Roles of various clinical trial entities (e.g., CROs, sponsors, regulatory authority)	
4H	Site initiation and close-out activities	
4I	Site staff qualifications	
4J	Study close-out activities	
5	**Study and Site Management**	**22**
5A	Communication documentation requirements between all study entities	
5B	Content of contract and study budget	
5C	Equipment and supplies use and maintenance	
5D	Investigational product accountability and documentation requirements	
5E	Study staff training procedures and documentation requirements	
5F	Investigational product characteristics, labeling requirements, and packaging	
5G	Investigational product shipment	
5H	Investigational product storage	
5I	Non-compliance management	
5J	Project timelines (e.g., data lock, enrollment period, recruitment/retention)	

5K	Purpose of and process(es) for protocol compliance	
5L	Sample collection, processing, shipment, and storage requirements	
5M	Subject compliance assessment	
5N	Subject responsibilities for study participation and visit activities	
5O	Vendor management	
6	**Data Management and Informatics**	**15**
6A	Data management activities including data privacy	
6B	Elements and purposes of data collection tools (e.g., eCRF, EDC, IWRS blinding)	
6C	Elements of and process for data query	
6D	Reporting requirements for pharmacovigilance and/or product/device vigilance (e.g., CIOMS, IDMC/DSMB, safety databases)	
6E	Essential Documents for the conduct of a clinical trial (e.g., paper/electronic, trial master file)	
6F	Record retention, certified copy, and destruction practices and requirements	
6G	Source data review (SDR) and source data verification (SDV) purpose and process	
6H	Study documentation practices and requirements (Accurate, Legible, Complete, Original, Attributable, Contemporaneous, Consistent, Enduring, Available (ALCOA+))	

TASK STATEMENTS

1. Assess subject compliance
2. Collect, record, and report accurate and verifiable data within applicable timeframe
3. Comply with IRB/IEC requirements
4. Comply with subject privacy regulations
5. Conduct prescreening activities with potential study subjects
6. Conduct and schedule subject visits
7. Confirm that investigational staff is delegated appropriately
8. Coordinate protocol and/or protocol amendments through appropriate approval processes (e.g., IRB/IEC, sponsor, regulatory authority)
9. Create, document, and/or implement corrective and preventive action (CAPA) plans
10. Develop and/or follow a recruitment strategy
11. Develop and/or implement education plan and/or tools for study-related activities for subjects

12. Develop and/or review informed consent form
13. Develop or participate in protocol training, and document
14. Develop source document templates
15. Develop trial management tools (e.g., subject study calendar, retention material)
16. Differentiate the types of adverse events that occur (e.g., serious vs non-serious, expected vs unexpected)
17. Document reasons for subject discontinuation (e.g., causes, contact efforts)
18. Ensure access to source (electric/paper) data by authorized parties, and protect confidentiality by preventing unauthorized access
19. Ensure adequate consent and documentation of the informed consent process
20. Ensure and document medical care for study subjects, as applicable
21. Ensure and maintain consistency between the site standard operating procedures (SOPs) and the study requirements
22. Ensure appropriate reporting and documentation of adverse event(s)
23. Confirm appropriate staff, facility, and equipment availability throughout the study
24. Ensure assessment and documentation of subject safety during study participation
25. Ensure investigator/site protocol compliance
26. Ensure IRB/IEC review/written approval of study and study documents
27. Identify monitoring activities are conducted according to plan
28. Ensure proper collection, processing, and shipment of specimens (e.g., centrifuge, preparation of slides, freezing, refrigeration)
29. Ensure proper inventory (including expiration), storage, handling, and disposition of investigational product and related supplies
30. Ensure the assessment, management, and review of subject laboratory values, test results, and alerts
31. Ensure the management of safety risks at the site (e.g., clinical holds, product recalls)
32. Ensure timely review of safety data
33. Escalate significant issues/concerns as appropriate
34. Evaluate study for feasibility (site determining ability to successfully conduct the study)
35. Facilitate response to post-audit/inspection findings
36. Follow up on and communicate regarding monitoring/site visit findings
37. Identify and minimize potential risks to subject safety
38. Identify and/or address potential ethical issues (suspected fraud and misconduct) involved with study conduct (as referenced in ICH GCP and applicable local regulations)
39. Identify and/or explain study design
40. Identify the role and proper composition of IRB/IECs
41. Identify the safety and expected/unexpected therapeutic effects of the investigational product using various study documents including the protocol and IB
42. Implement plan of action for management of adverse event(s) (e.g., stop

investigational product, retest, treat subject)
43. Implement protocol amendments
44. Inform study subjects of trial results, in accordance with regulatory requirements
45. Inform the sponsor and/or IRB/IEC of any protocol deviations and document as appropriate
46. Instruct subjects on proper use of investigational product
47. Maintain blinding and unblinding procedures of investigational product
48. Maintain Essential Documents required for study conduct
49. Maintain follow-up to determine resolution of adverse event(s)
50. Maintain randomization procedures of investigational product
51. Maintain study-related logs (e.g., site signature log, screening log)
52. Manage study records retention and availability
53. Manage study supplies (e.g., lab kits, case report forms)
54. Participate in the informed consent process(es)
55. Perform and/or verify equipment calibration and maintenance
56. Perform query resolution
57. Plan, conduct and/or participate in training of the investigational staff
58. Prepare and/or submit documents for review/approval by IRB/IEC, sponsor, and/or other regulatory authority
59. Prepare and/or submit study summary and/or close-out letter for IRB/IEC
60. Prepare for and/or participate in study site audits and inspections
61. Prepare for, coordinate, and/or participate in study start-up activities
62. Prepare for, facilitate, and/or participate in interim and close-out monitoring activities visit(s) (including onsite, remote, and risk-based)
63. Reconcile and maintain accountability of investigational product and related supplies
64. Reconcile and administer payments to participants per clinicial trial agreement
65. Reevaluate the recruitment strategy as needed
66. Review and submit completed eCRF/CRF
67. Review the Investigator Brochure
68. Schedule, coordinate, and/or participate in pre-study and site initiation visits
69. Screen trial subjects

© 2024. Association of Clinical Research Professionals. All rights reserved. No part of this publication may be reproduced or transmitted in any form or by any means without written permission.