ACRP ACADEMY OF CLINICAL RESEARCH PROFESSIONALS

## 2024 EXAMINATION CONTENT OUTLINE:

# ACRP-CP® CERTIFICATION

The Exam Content Outline (ECO) serves as a foundational guide for candidates preparing for the ACRP Certified Professional (ACRP-CP®) 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-CP® 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 Professional certification, please visit the ACRP website.

# EXAMINATION CONTENT OUTLINE

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| **1** | **Ethical and Participant Safety Considerations** | **18** |
| 1A | Standard of care vs. clinical research protocol requirements | |
| 1B | Clinical equipoise vs. therapeutic misconception | |
| 1C | Content of the key documents ensuring subject protection (e.g., IB, protocol, informed consent documents) | |
| 1D | Considerations for vulnerable populations | |
| 1E | Past and current ethical issues in clinical research (e.g., diversity) | |
| 1F | Risks vs. benefits in the selection of research subjects | |
| 1G | Unblinding procedures | |
| 1H | Confidentiality and privacy | |
| 1I | Elements and process of informed consent/assent | |
| 1J | Protocol deviation/violation identification, documentation, and reporting processes | |
| 1K | Recruitment and retention plan/strategies | |
| 1L | Safety monitoring and reporting | |
| 1M | Subject discontinuation criteria/procedures | |
| 1N | Conflict of interest in clinical research | |
| 1O | Fraud and misconduct | |
| **2** | **Clinical Research Standards and Guidelines** | **17** |
| 2A | Stakeholders and regulatory institutions and frameworks in clinical research | |
| 2B | Phases of clinical research | |
| 2C | Regulatory reporting requirements (e.g., pre- and post-approval, safety) | |
| 2D | Standards for handling hazardous goods, materials, and biological samples | |
| 2E | Audit and inspection processes (preparation, participation, documentation, and follow-up) | |
| 2F | IRB/IEC role, composition, purpose, and reporting requirements | |
| 2G | Protocol submission, approval, and amendment processes | |
| 2H | Efficacy and safety evaluation milestones (e.g., interim analysis result, DSMB review) | |
| **3** | **Clinical Trial Operations (GCPs)** | **25** |
| 3A | Conduct, documentation, and management of clinical trials | |
| 3B | Study staff roles, training, qualifications, and delegation of responsibilities | |
| 3C | Control, storage, and dispensation of investigational products/devices | |
| 3D | Adverse event classification, reporting, and management | |
| 3E | Study reporting requirements (e.g., SAEs, deviations, INDs, IRB) | |
| 3F | Study monitoring | |
| 3G | Audits and inspections | |
| 3H | Protocol/GCP deviation identification and management | |

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| 3I | IRB/IEC requirements such as submission, review, and approval of documents | |
| 3J | Corrective and preventive action (CAPA) processes | |
| 3K | Source data review and verification | |
| 3L | Site selection activities | |
| 3M | Principal investigator responsibilities | |
| 3N | Roles of various clinical trial entities (e.g., CROs, sponsors, regulatory authority) | |
| 3O | Site initiation, maintenance, and closeout activities | |
| **4** | **Study and Site Management** | **21** |
| 4A | Quality management activities in the conduct of clinical research | |
| 4B | Responsibilities and obligations involved in the conduct of a clinical trial | |
| 4C | Oversight requirements of PIs, sponsors, contract research organizations (CROs), and regulatory authorities | |
| 4D | Contractual agreements (e.g., budgets, clinical trial agreement) | |
| 4E | Maintenance and use of equipment and supplies | |
| 4F | Investigational product/device accountability and documentation requirements | |
| 4G | Investigational product/device reference materials (e.g., Investigator brochure, instructions for use, user manual) | |
| 4H | Non-compliance management | |
| 4I | Sample collection, storage, disposal, and shipment requirements | |
| 4J | Assessment of subject compliance | |
| 4K | Study evaluation for feasibility | |
| 4L | Record retention and destruction practices and requirements | |
| 4M | Essential documents for the conduct of a clinical trial (e.g., trial master file) | |
| **5** | **Research Design and Data Management** | **19** |
| 5A | Clinical trial design (e.g., double-blind, cross-over, randomization) | |
| 5B | Elements of a protocol | |
| 5C | Elements and purpose of an Investigational Brochure (IB) and Instructions for Use | |
| 5D | Rationale for subject eligibility requirements | |
| 5E | Study objectives, hypotheses, and end points/outcomes | |
| 5F | Basic concepts of biostatistics and informatics in research | |
| 5G | Flow of data throughout clinical research | |
| 5H | Data collection, correction, and queries (e.g., electronic data capture, audit trails) | |
| 5I | Data quality systems and privacy principles | |
| 5J | Study documentation practices (ALCOA-C) | |

## TASK STATEMENTS

1. Review data quality and/or source data/document review (SDR) and/or verification (SDV)
2. Assess compliance and documentation of consent process(es)
3. Assess protocol compliance (e.g., visits, procedures, reporting)
4. Verify qualifications of IRB/IEC
5. Assess qualifications of the investigational site, site staff, and principal investigator
6. Assess subject compliance (e.g., protocol, investigational product/device, diaries/logs)
7. Assess, manage, and/or review subject test results/safety data (e.g., timeliness, accuracy, frequency, response)
8. Collect, maintain, verify, and/or store regulatory essential documents
9. Compare and contrast clinical care and clinical management of research participants (e.g., standard of care vs. protocol requirements)
10. Comply with electronic data system requirements (e.g., passwords, access, electronic signatures)
11. Comply with IRB/IEC requirements such as submission, review, and approval of documents
12. Comply with randomization procedures of the protocol
13. Conduct and document the informed consent process(es)
14. Conduct quality control/assurance activities in the conduct of clinical research
15. Continually evaluate subject recruitment and retention strategy, and study progress
16. Coordinate protocol and/or protocol amendments through appropriate approval processes (e.g., IRB/IEC, sponsor, regulatory authority)
17. Create, document, and/or implement corrective and preventative action (CAPA)
18. Develop and/or manage resources necessary to conduct a study (the financial, timeline, and cross- disciplinary personnel)
19. Develop and/or review informed consent form
20. Develop and/or review unblinding procedures as applicable
21. Develop, review, and/or implement study plans and/or tools (e.g., subject materials, recruitment plan, lab manuals)
22. Evaluate and comply with the regulatory requirements pertaining to research
23. Evaluate and/or explain the benefits versus risks for study subject protections
24. Evaluate potential conflicts of interest
25. Evaluate reasons for subject discontinuation (e.g., causes, contact efforts)
26. Evaluate study for feasibility and practicality of protocol execution (e.g., site/sponsor determining ability to successfully conduct the study)
27. Evaluate the conduct and management of clinical research studies (e.g., protocol, study plan, monitoring plan, data management plan)
28. Identify and address ethical issues involved with study conduct
29. Identify and comply with the requirements for human subject protections and privacy

30. Identify and/or describe study design (e.g., hypotheses, objective(s), endpoints)
31. Identify and/or implement risk management strategies (e.g., subject, investigational product/device, data handling)
32. Identify and/or manage adverse events (e.g., treat subject, rechallenge, adjust treatment)
33. Identify roles and responsibilities as defined by GCP guidelines
34. Identify the ICH/GCP requirements for data collection, corrections, and queries
35. Identify the process and purpose for monitoring of the study
36. Identify vulnerable populations and the additional safeguards required
37. Identify, document, communicate, and follow up on site issues
38. Identify, investigate, and report potential fraud and misconduct
39. Identify, manage, document, and report any deviations from the protocol
40. Implement the administrative and/or clinical tasks for protocol amendments
41. Inform study participants of study results, in accordance with regulatory requirements
42. Instruct subjects on protocol requirements (e.g., investigational product/device, diaries, visits)
43. Integrate risk-based approach to quality management and monitoring
44. Maintain and/or review study related logs (e.g., site signature/delegation log, screening log)
45. Manage and/or review investigational product/device accountability, shipment, storage, dispensing, use, and recall according to the research protocol
46. Manage source data/documents according to Attributable Legible Contemporaneous Original Accurate-Complete (ALCOA-C) standards
47. Manage study records (e.g., retention/storage, availability)
48. Obtain and/or confirm presence of a signed indemnification/insurance, contracts, and/or budgets
49. Oversee vendors (e.g., labs, IRB/IEC, technology, subject matter recruitment, CRO)
50. Participate in audits and inspections (e.g., prepare, support, respond)
51. Perform and/or verify equipment calibration and maintenance
52. Prepare, conduct, and/or participate in site monitoring (onsite, centralized, or remote)
53. Prepare, support, and/or participate in closeout activities (site or study)
54. Provide or participate in study training (e.g. site initiation visit, IM, webinar)
55. Record and/or review data for accuracy and verifiability (e.g., completed eCRF/CRF)
56. Review the protocol and supporting documentation (e.g., investigators brochure, instructions for use, package insert)
57. Review the safety and expected therapeutic effects of the investigational product/device (e.g., using the investigator brochure or package insert)
58. Screen and/or confirm eligibility for research subjects
59. Verify appropriate staff, facility, supplies, and equipment availability throughout the study
60. Verify that inclusion and exclusion criteria assure human subject protection