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SOCRA CCRP Exam Syllabus Topics:

Topic	Details
Topic 1	• Research Study Start-Up: This section of the exam measures the skills of Clinical Research Coordinators and covers the initial planning and setup of a clinical trial. It involves coordinating the development of the study protocol, ensuring it considers ethical guidelines and regulatory pathways like IND or IDE. It also includes creating essential study documents like informed consent forms and case report forms. The domain covers obtaining necessary approvals from stakeholders like the IRB and sponsor, selecting study sites, training staff, and ensuring the study's compliance with various laws. Additionally, it involves obtaining the research product and preparing all necessary tools and documentation for the study's commencement.|Research Study Implementation: This section of the exam measures the skills of Clinical Research Associates and covers the active management and execution of the clinical trial. It focuses on following the study protocol and standard operating procedures, managing the investigational product, and ensuring ongoing regulatory compliance. The domain includes identifying, documenting, and reporting any study anomalies such as adverse events or protocol deviations. It also involves managing subject recruitment, consent, and retention, as well as maintaining all study records and essential documents. Furthermore, it covers communicating with all study stakeholders and participating in study audits to ensure quality and adherence to regulations.
Topic 2	• Research Study Closure: This section of the exam measures the skills of Clinical Research Coordinators and covers the activities required to properly conclude a clinical trial. It involves participating in the study closeout visit to verify documentation and account for the investigational product. The domain also includes developing and submitting final closure reports to the IRB, study sponsor, regulatory authorities, and clinicaltrials.gov. Finally, it covers the procedures for archiving study records.

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q31-Q36):

NEW QUESTION # 31
In a completed multi-site Phase I drug study using remote EDC, who ensures the system complies with accuracy and reliability requirements?

- A. Institution
- B. Investigator
- C. Regulatory authority
- D. Sponsor

Answer: D

Explanation:
* ICH E6(R2) 5.5.3:Sponsors are responsible for validating computerized systems used in trials.
Investigators ensure proper data entry, but system compliance lies with sponsor.
References:ICH E6(R2), §5.5.3.

NEW QUESTION # 32
In accordance with the Belmont Report, obtaining voluntary informed consent from subjects prior to enrolling them in a clinical trial is an example of which of the following ethical principles?

- A. Beneficence
- B. Do no harm
- C. Justice
- D. Respect for persons

Answer: D

Explanation:
TheBelmont Report (1979)establishedthree key ethical principles:
* Respect for Persons:Requires informed consent, recognition of autonomy, and protection of vulnerable individuals.
* Beneficence:Obligation to maximize benefits and minimize harm.
* Justice:Ensuring fairness in subject selection and distribution of research burdens/benefits.
Voluntary informed consent embodiesRespect for Persons, as subjects are given adequate information and freedom of choice. "Do no harm" (A) is a Hippocratic principle but not Belmont terminology.
Thus, the correct answer isB (Respect for persons).
References:
The Belmont Report (1979), Part B: Basic Ethical Principles.

NEW QUESTION # 33
According to 21 CFR Part 11, each electronic signature must be unique and:

- A. Transferable to family
- B. Cannot be reused or reassigned
- C. Identical to handwritten signature
- D. Reassignable after validation

Answer: B

Explanation:
* 21 CFR 11.100(a):Requires that electronic signatures be "unique to one individual and shall not be reused or reassigned to anyone else."

* This ensures accountability and audit trail integrity.
References:21 CFR 11.100(a).

NEW QUESTION # 34
During an audit of a sponsor, the following documents and activities were reviewed: the protocol, applicable regulatory requirements, and compliance with Good Clinical Practice (GCP). What additional documents must be reviewed during the sponsor audit?

- A. Standard Operating Procedures (SOPs)
- B. Personnel records
- C. Financial reports
- D. Audit reports

Answer: D

Explanation:
Sponsor audits ensure systems comply with GCP.
* ICH E6(R2) 5.19.3:"The sponsor's auditing procedures should include a review of quality assurance audits and audit reports."
* Audit reports document findings from independent evaluations and are essential for ensuring compliance.
SOPs (A) are reviewed during audits but are not mandated as standalone "audit review documents." Personnel files (B) and financial reports (C) are not required under GCP auditing provisions.
Correct answer:D (Audit reports).
References:
ICH E6(R2), §5.19.3.

NEW QUESTION # 35
Which of the following is considered a source document?

- A. The subject instruction sheet
- B. The protocol
- C. Standard operating procedures (SOPs)
- D. Pharmacy dispensing records

Answer: D

Explanation:
Source documentsare the original records where trial data are first recorded, from which Case Report Form (CRF) entries are verified.
* ICH E6(R2) 1.52:Defines source documents as "original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, pharmacy dispensing records, recorded data from automated instruments, etc.)."
* ICH E6(R2) 8.3.13:Requires maintenance of "source documents" to verify data integrity and allow monitoring/audits.
Pharmacy dispensing records (D) fit this definition, as they show initial data on investigational product dispensing and accountability.
In contrast, subject instruction sheets (A) are communication tools, SOPs (B) are procedural guides, and the protocol (C) is a governing document, none of which qualify as original data records.
Therefore, the correct answer isD (Pharmacy dispensing records).
References:
ICH E6(R2), §1.52 (Definition of source documents).
ICH E6(R2), §8.3.13 (Source documents in essential documentation).

NEW QUESTION # 36
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