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SOCRA CCRP Exam Syllabus Topics:

Topic	Details
Topic 1	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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 (Q38-Q43):

NEW QUESTION # 38

According to 21 CFR Part 11, each electronic signature must be unique and:

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

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 # 39

In accordance with the CFR, which of the following statements regarding the informed consent document is correct?

- A. It does not identify some of the applicable mandated basic elements
- **B. It identifies all of the applicable mandated basic elements**
- C. It is signed and dated by the subject's legally authorized representative
- D. It is signed and dated by the IRB/IEC chair

Answer: B

Explanation:

The informed consent document (ICD) is a cornerstone of ethical clinical research, ensuring voluntary participation and protection of subject rights.

* 21 CFR 50.25(a): Requires the consent form to contain all basic elements, including study purpose, risks, benefits, alternatives, confidentiality, compensation, and voluntariness.

* ICH E6(R2) 4.8.10: Expands on these requirements, ensuring the ICD contains every mandated element without omission.

Thus, the correct statement is that the ICD must include all applicable mandated basic elements (D).

Options A and B confuse who signs—subjects or legally authorized representatives sign when applicable, not the IRB chair. Option C is incorrect because leaving out elements would violate compliance.

Correct answer: D.

References:

21 CFR 50.25(a).

ICH E6(R2), §4.8.10.

NEW QUESTION # 40

In accordance with 21 CFR Part 11, a closed electronic records system must do all EXCEPT:

- A. Maintain accurate records throughout retention
- B. Generate audit trails
- **C. Print a complete paper copy**
- D. Customize access rights

Answer: C

Explanation:

* 21 CFR 11.10: Requires validation, audit trails, secure access, but does not mandate printing capability.

Thus, (D) is the exception.

References: 21 CFR 11.10.

NEW QUESTION # 41

Before approving a research protocol, an IRB/IEC must determine compliance with which of the following requirements?

- A. A plan for the publication of study results is in place
- **B. The selection of subjects is equitable**
- C. The investigator has adequate access to patients eligible for the trial
- D. The sponsor is qualified to provide oversight of the trial

Answer: B

Explanation:

IRB/IEC review focuses on ethical protection of human subjects. Equitable subject selection is a cornerstone principle.

* 45 CFR 46.111(a)(3): "In order to approve research... the IRB shall determine that: Selection of subjects is equitable."

* ICH E6(R2) 3.1.2: "The IRB/IEC should safeguard the rights, safety, and well-being of all trial subjects... with particular attention to trials that may include vulnerable subjects." Publication plans (A) are not required by IRBs. Access to patients (C) and sponsor qualifications (D) are evaluated by sponsors, not IRBs. The IRB's role is ensuring fairness, minimizing coercion, and protecting vulnerable populations.

Thus, the correct answer is B (The selection of subjects is equitable).

References:

45 CFR 46.111(a)(3) (Equitable subject selection).

ICH E6(R2), §3.1.2 (IRB/IEC role).

NEW QUESTION # 42

Which of the following statements about the investigator's brochure is correct?

- A. It includes financial disclosure information from investigators
- B. It provides documents that permit the evaluation of the conduct of the study and the quality of the data
- C. It consists of the instructions for the investigator to conduct the study
- **D. It contains a summary of the pharmacological and toxicological effects of the drug in animals, and to the extent known, in humans**

Answer: D

Explanation:

The Investigator's Brochure (IB) is a critical regulatory document designed to provide investigators with comprehensive knowledge about an investigational product.

* ICH E6(R2) 7.1: Defines the IB as "a compilation of the clinical and nonclinical data on the investigational product(s) that are relevant to the study of the product(s) in human subjects."

* ICH E6(R2) 7.2.2: Specifies the IB should contain a summary of pharmacological, toxicological, pharmacokinetic, and metabolic studies in animals, as well as results from previous human experience.

* The purpose is to allow investigators to make risk-benefit assessments, support protocol design, and ensure subject safety.

Incorrect options:

* A (instructions to conduct study) describes the protocol, not the IB.

* C (financial disclosures) are required under 21 CFR 312.63, not part of the IB.

* D refers to trial master file/essential documents, not the IB.

Therefore, the IB's defining function is to provide a scientific summary of preclinical and clinical data supporting safe human use.

References:

ICH E6(R2), §7.1, §7.2.2.

NEW QUESTION # 43

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