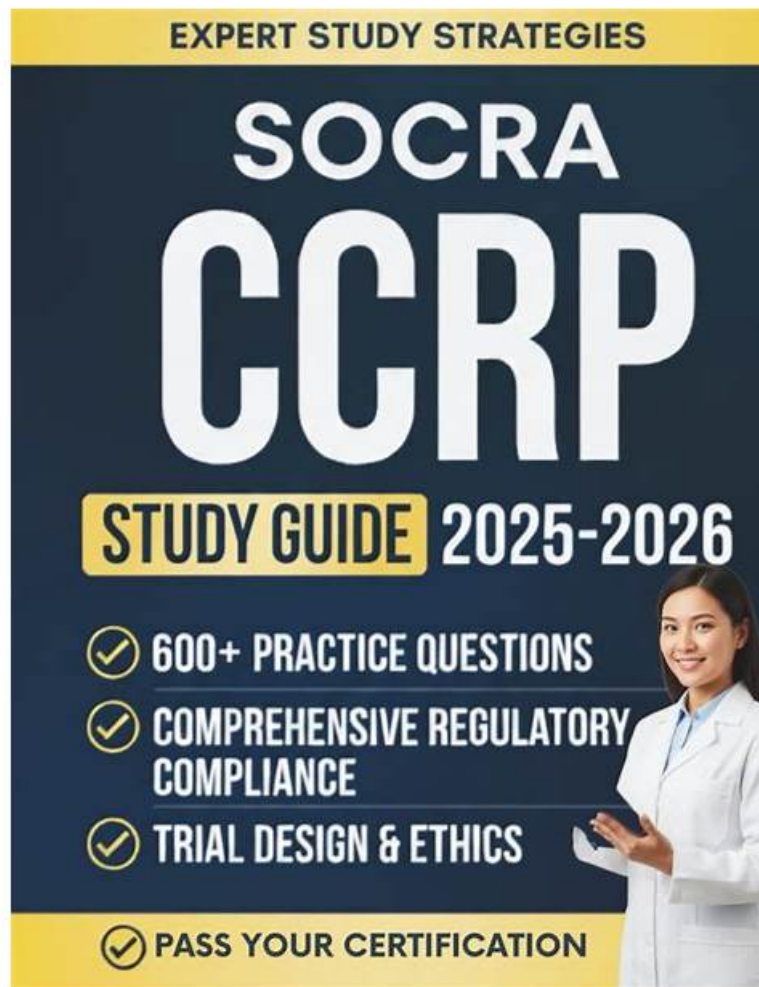


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SOCRA CCRP Exam Syllabus Topics:

Topic	Details
Topic 1	<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.
Topic 2	<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.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q114-Q119):

NEW QUESTION # 114

Protecting prisoners' rights to voluntarily participate in research is an example of which Belmont principle?

- A. Dignity
- **B. Respect for Persons**
- C. Justice
- D. Beneficence

Answer: B

Explanation:

* Belmont Report: "Respect for Persons" incorporates two ethical convictions: treating individuals as autonomous agents and protecting those with diminished autonomy (e.g., prisoners).

* Prisoners require special safeguards because of restricted liberty and potential coercion.

References: Belmont Report (1979).

NEW QUESTION # 115

During the closeout visit, a monitor is completing the documentation of reconciliation of investigational product. All packaging, as well as the used and unused investigational product, are being returned to the sponsor for disposition. Which of the following documents would NOT be required to be filed at the research site?

- A. Investigational product inventory forms
- B. Records of investigational product shipment
- **C. A certificate of investigational product destruction**
- D. Investigational product accountability forms

Answer: C

Explanation:

Investigators must document the receipt, use, return, or alternative disposition of investigational product (IP).

* ICH E6(R2) 4.6.3: Requires investigators to maintain records of IP delivery, inventory, use by subjects, and return/disposition.

* ICH E6(R2) 8.2.14-8.2.16: Essential documents include shipment records, accountability logs, and inventory records. However, certificates of destruction are generated and retained by the sponsor (or authorized destruction facility), not required at the site unless the destruction occurred there. In this scenario, all IP was returned to the sponsor, so no destruction certificate would exist at the site.

Thus, the correct answer is D (Certificate of destruction).

References:

ICH E6(R2), §4.6.3 (Investigator product accountability).

ICH E6(R2), §8.2.14-8.2.16 (Essential documents).

NEW QUESTION # 116

A sponsor is permitted to charge for an investigational drug but must provide what documentation?

- A. Orphan product evidence
- B. IRB attestation of institutional cost burden
- C. Evidence of potential clinical benefit and significant advantage
- D. CMS approval letter

Answer: C

Explanation:

* 21 CFR 312.8(b): Sponsors may charge for investigational drugs only if they demonstrate that the drug provides potential clinical benefit and a significant advantage over existing therapy.

* FDA must approve charging requests.

References: 21 CFR 312.8(b).

NEW QUESTION # 117

Which of the following entities, if any, must provide an approval before an investigator may enroll subjects in a quality-of-life research questionnaire study?

- A. The FDA or another regulatory authority
- B. No approvals are necessary if no pharmaceutical drugs are involved
- C. The IRB/IEC
- D. The Department of Health and Human Services

Answer: C

Explanation:

Even if a study does not involve drugs, devices, or biologics, it still involves human subjects and therefore requires ethical review by an IRB/IEC.

* 45 CFR 46.109(a): "An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy."

* ICH E6(R2) 3.1.2: "The IRB/IEC should safeguard the rights, safety, and well-being of all trial subjects." Quality-of-life (QOL) studies may involve surveys, interviews, or questionnaires, but since they involve human participants, they are subject to human research protection regulations. FDA involvement is not required unless drugs or devices are tested. Similarly, HHS approval is not required unless the study is federally funded.

Thus, the correct answer is C (The IRB/IEC).

References:

45 CFR 46.109(a) (IRB review of research).

ICH E6(R2), §3.1.2 (IRB/IEC role in subject protection).

NEW QUESTION # 118

In accordance with the CFR, a sponsor must submit a protocol amendment to the FDA for which of the following?

- A. A significant change in an investigator's financial interest in the investigational product
- B. The addition of a sub-investigator with the scientific training and expertise to conduct the investigation
- C. A change in the manufacturing site for the investigational product
- D. The addition of a new test that is intended to improve monitoring the subject for an adverse effect

Answer: C

Explanation:

The U.S. Code of Federal Regulations (CFR) specifies when sponsors must notify FDA of changes to investigational drug studies under 21 CFR 312.30. A protocol amendment is required if there is:

A change to the protocol (e.g., objectives, design, subject population, dosing, or procedures).

The addition of a new investigator.

A change in the chemistry, manufacturing, or controls (CMC) that could significantly affect product quality or safety.

Among the listed options, a change in the manufacturing site (D) directly falls under significant manufacturing changes, requiring FDA submission. Changes in investigator financial interests (B) are covered under 21 CFR 54 and reported separately, not as protocol amendments. Addition of a sub-investigator (C) does not require a formal amendment, only site-level documentation and delegation log update. Addition of a monitoring test (A) may affect the protocol, but not necessarily mandate an amendment unless it changes objectives or subject safety endpoints.

Therefore, the correct answer is D. This ensures FDA oversight of product safety, efficacy, and compliance with CMC standards before investigational use.

References:

21 CFR 312.30 (Protocol amendments).

21 CFR 312.23(a)(7) (Chemistry, manufacturing, and controls information).

NEW QUESTION # 119

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