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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.
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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q69-Q74):

NEW QUESTION # 69

A physician wants to conduct research using an approved/ marketed cardiac stent for use in the carotid artery, which is not an indication for which the device is approved. In this case, the physician must obtain which of the following?

- A. IRB/IEC approval and an FDA IND
- **B. IRB/IEC approval and an FDA IDE**
- C. IRB/IEC and manufacturer approval
- D. The Office for Human Research Protections (OHRP) and manufacturer approvals

Answer: B

Explanation:

When a physician investigates a medical device for a new use (off-label indication), FDA regulations classify this as a Significant Risk Device Study, requiring an Investigational Device Exemption (IDE) in addition to IRB approval.

* 21 CFR 812.20(a): "A sponsor shall submit an application to FDA for an investigational device exemption (IDE) if the device is to be used in a clinical investigation to determine safety and effectiveness."

* 21 CFR 812.2(b): Significant Risk device studies require both FDA and IRB approval before initiation.

An IND (B) applies to drugs and biologics, not devices. Manufacturer permission (A, D) is not a regulatory requirement, although collaboration may be necessary. OHRP approval is not applicable.

Thus, the correct answer is C (IRB/IEC approval and an FDA IDE).

References:

21 CFR 812.20(a) (IDE submission requirements).

21 CFR 812.2(b) (Significant risk device studies).

NEW QUESTION # 70

An IND application must contain all EXCEPT:

- A. A cover sheet

- **B. Financial disclosure information**
- C. Investigator's brochure
- D. Chemistry, manufacturing, and control information

Answer: B

Explanation:

* 21 CFR 312.23(a): Requires cover sheet, CMC information, and IB.

* Financial disclosure is required separately under 21 CFR 54, not part of IND content.

References: 21 CFR 312.23(a); 21 CFR 54.

NEW QUESTION # 71

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

Answer: A

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 # 72

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

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

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 # 73

Protocol increases drug dose by 20%. Baseline: 370 mg/m². New dose = ?

- A. 400 mg/m²
- B. 420 mg/m²
- C. 444 mg/m²
- D. 492 mg/m²

Answer: C

Explanation:

$$370 \times 1.20 = 444 \text{ mg/m}^2$$

Accurate dosing calculations are critical for protocol adherence and patient safety.

References: Standard pharmacology dose adjustment principles; ICH E6(R2) §4.5.1.

NEW QUESTION # 74

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