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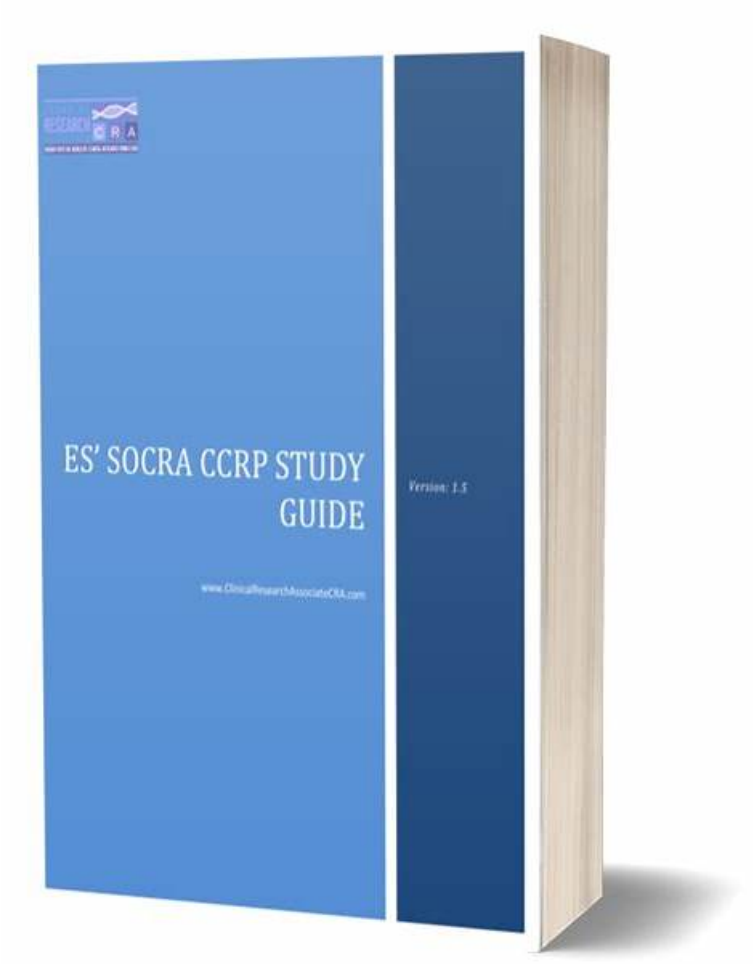


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## SOCRA CCRP Exam Syllabus Topics:

| Topic | Details |
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| 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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# CCRP Valid Test Blueprint - How to Prepare for SOCRA CCRP Exam

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# SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q63-Q68):

**NEW QUESTION # 63**
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 wouldNOTbe required to be filed at the research site?

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

**Answer: D**

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 destructionare 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 isD (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 # 64**
In accordance with ICH/GCP Guidance, how long should an IRB/IEC retain all relevant study-related records pertaining to the IRB/IEC's review after a trial has been completed?

- A. At least 3 years
- B. Indefinitely
- C. At least 15 years
- D. Until the regulatory authority has approved the investigational product for use

**Answer: A**

Explanation:
IRBs/IECs must retain records to permit evaluation of compliance.
* ICH E6(R2) 3.4.2:"IRB/IEC should retain all relevant records (e.g., written procedures, membership lists, lists of occupations/affiliations of members, submitted documents, minutes of meetings, and correspondence) for at least3 years after completion of the trial." Extended retention (B-D) may occur institutionally, but ICH minimum is3 years.
Correct answer:A (At least 3 years).
References:
ICH E6(R2), §3.4.2.

**NEW QUESTION # 65**
An investigator received an updated informed consent form (ICF) from the sponsor for a study closed to enrollment. Subjects are only in long-term follow-up. The change related to frequent radiation imaging at screening, with no change to drug safety profile. Who must the investigator notify first?

- A. The IRB/IEC
- B. No notification is required
- C. Sub-investigators
- D. Participants in long-term follow-up

**Answer: A**

Explanation:
* 21 CFR 56.109(a):IRBs must review all changes to informed consent before implementation.
* ICH E6(R2) 4.8.2:If new information could affect willingness to continue, consent forms must be revised and approved by the IRB.
Even though screening is closed, the IRB/IEC must review the updated form before any subject re-consenting.
References:21 CFR 56.109(a); ICH E6(R2) §4.8.2.

**NEW QUESTION # 66**
Which of the following statements about the initial IND application submission by a sponsor to the U.S. Food and Drug Administration is correct?

- A. It is an application to export the investigational drug
- B. It includes the rationale for human testing and a description of the general investigational plan
- C. It includes a disclosure of the financial interests and arrangements of clinical investigators
- D. It is an application for the sponsor to sell the drug for profit

**Answer: B**

Explanation:
AnInvestigational New Drug (IND) applicationprovides FDA with data to justify human testing.
* 21 CFR 312.23(a)(3):The IND must contain "a description of the general investigational plan, including the rationale for the drug or the research study."
* The IND also includes preclinical safety data, manufacturing details, investigator qualifications, and study protocols.
Financial disclosures (D) are reported separately under21 CFR Part 54, not as part of the initial IND. Export applications (A) are covered under21 CFR 312 Subpart E. Profit sales (C) are not permitted under INDs.
Thus, the correct answer isB (Rationale and plan for human testing).

References:
21 CFR 312.23(a)(3) (IND contents).
21 CFR 312.20 (General IND requirements).

**NEW QUESTION # 67**
In accordance with 45 CFR 46, in addition to the Office for Human Research Protections (OHRP), a suspension of IRB/IEC approval must be reported to which of the following?

- A. The local hospital's medical director
- B. The local hospital's bioethics committee
- C. The appropriate institutional officials
- D. The Scientific Review Committee

**Answer: C**

Explanation:
If IRB/IEC approval is suspended or terminated, reporting is required to protect oversight and accountability.
* 45 CFR 46.113:"An IRB shall notify theinstitutional officials, the department or agency head, and OHRP(when applicable) of any suspension or termination of IRB approval." This ensures transparency and institutional responsibility for compliance. Internal hospital committees or directors (A, C, D) are not mandated reporting entities.
Thus, the correct answer isB (Appropriate institutional officials).
References:
45 CFR 46.113 (Suspension or termination of IRB approval).

**NEW QUESTION # 68**
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