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## SOCRA CCRP Exam Syllabus Topics:

Topic	Details
Topic 1	<ul style="list-style-type: none"><li>• <b>Research Study Start-Up:</b> 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.</li><li>• <b>Research Study Implementation:</b> 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.</li></ul>

Topic 2	<ul style="list-style-type: none"> <li>• <b>Research Study Closure:</b> 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.</li> </ul>
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### SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q105-Q110):

#### NEW QUESTION # 105

According to the CFR and the ICH GCP Guideline, which of the following must be submitted to the IRB after completion of the trial at the site?

- A. The data safety monitoring summary
- **B. The final report**
- C. The final subject enrollment log
- D. The monitoring close-out visit report

**Answer: B**

Explanation:

When a trial ends at a site, the investigator has an obligation to submit a final report to the IRB/IEC. This is outlined in both ICH and CFR:

ICH E6(R2) 4.13: "Upon completion of the trial, the investigator should provide the IRB/IEC with a summary of the trial's outcome."

21 CFR 312.66: Requires investigators to "report to the IRB all changes in the research activity and all unanticipated problems involving risk, and to provide reports at the end of the study." The final report provides closure and documentation that the study was conducted ethically and in compliance with regulatory standards. Other documents listed in the options (monitoring reports, DSMB summaries, subject logs) may be retained by the sponsor or site, but they are not mandated for IRB submission.

Thus, the correct answer is A (Final Report). This ensures the IRB/IEC has an accurate record of study completion, outcome, and compliance with ethical oversight.

References:

ICH E6(R2), §4.13 (Final reporting to IRB/IEC).

21 CFR 312.66 (IRB review and reporting).

#### NEW QUESTION # 106

Which case history documents must be at both sponsor and site?

- A. Study visit notes
- B. Medical records
- C. Signed informed consent forms
- **D. Case report forms (CRFs)**

**Answer: D**

Explanation:

\* ICH E6(R2) 1.11:CRFs are documents used to record protocol-required data reported to sponsor.

\* Sites keep originals; sponsor retains copies. Consent forms and medical records stay at site only.  
References: ICH E6(R2), §1.11.

#### NEW QUESTION # 107

The sponsor withdrew an IND due to safety. Who must be notified promptly, in addition to FDA?

- A. Site coordinator
- B. OHRP
- C. Investigational pharmacies
- D. Reviewing IRBs/IECs

**Answer: D**

Explanation:

\* 21 CFR 312.56(d): If an IND is withdrawn for safety, the sponsor must notify FDA and all participating investigators, who in turn notify IRBs.

\* Ensures subjects are protected and sites stop enrollment.

References: 21 CFR 312.56(d).

#### NEW QUESTION # 108

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

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

**Answer: C**

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 # 109

A clinical investigator received an honorarium from the sponsor of a covered study. At what payment value must this be reported?

- A. >\$25,000
- B. \$5,000
- C. \$10,000
- D. Any amount

**Answer: C**

Explanation:

\* 21 CFR 54.2(f) & 54.4(a): Requires disclosure of "significant payments of other sorts" (SPOOS) that exceed \$25,000 or equity interests exceeding \$50,000.

\* However, honoraria or consulting exceeding \$10,000 annually also trigger disclosure.

Thus, the reporting threshold is \$10,000.

References: 21 CFR 54.2(f), 54.4(a).

#### NEW QUESTION # 110

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