

# Pass Guaranteed Professional SOCRA - CCRP - Exam Certified Clinical Research Professional (CCRP) Objectives Pdf



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## SOCRA CCRP Exam Syllabus Topics:

Topic	Details
Topic 1	<ul style="list-style-type: none"><li>• 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 <a href="http://clinicaltrials.gov">clinicaltrials.gov</a>. Finally, it covers the procedures for archiving study records.</li></ul>

Topic 2	<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>
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## SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q69-Q74):

### NEW QUESTION # 69

A subject was instructed to do a glucose check 4 times a day for 10 days using an investigational glucose meter. The meter requires one new glucose test strip for each test. The subject received the meter along with 45 glucose test strips. How many unused test strips should the subject have after the 10 days?

- A. 0
- B. 1
- **C. 2**
- D. 3

**Answer: C**

Explanation:

This is a drug/device accountability calculation question, testing compliance with investigational product tracking.

\* The subject was instructed to perform 4 glucose checks per day.

\* Over 10 days, that equals 40 tests ( $4 \times 10 = 40$ ).

\* Each test requires 1 strip, so 40 strips used.

\* Subject was given 45 strips, leaving 5 unused after 10 days.

Investigators are responsible for maintaining accurate device/product accountability.

\* ICH E6(R2) 4.6.3: "The investigator/institution should maintain records of the product's delivery to the trial site, the inventory, the use by each subject, and the return to the sponsor or alternative disposition."

\* This ensures monitoring can confirm that product/device use aligns with the protocol and subject adherence.

Thus, the correct answer is B (5 unused test strips).

References:

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

### NEW QUESTION # 70

During an audit of a sponsor, the following documents and activities were reviewed: the protocol, applicable regulatory requirements, and compliance with Good Clinical Practice (GCP). What additional documents must be reviewed during the sponsor audit?

- A. Personnel records
- B. Standard Operating Procedures (SOPs)
- C. Financial reports
- **D. Audit reports**

**Answer: D**

Explanation:

Sponsor audits ensure systems comply with GCP.

\* ICH E6(R2) 5.19.3: "The sponsor's auditing procedures should include a review of quality assurance audits and audit reports."

\* Audit reports document findings from independent evaluations and are essential for ensuring compliance.

SOPs (A) are reviewed during audits but are not mandated as standalone "audit review documents." Personnel files (B) and financial reports (C) are not required under GCP auditing provisions.

Correct answer: D (Audit reports).

References:

ICH E6(R2), §5.19.3.

### NEW QUESTION # 71

In accordance with the CFR, the IRB/IEC membership must have:

- A. At least one cleric
- **B. At least one individual who is not affiliated with the institution**
- C. A majority of individuals whose primary area of expertise is nonscientific
- D. At least seven individuals

**Answer: B**

Explanation:

IRBs must be diverse and independent to protect human subjects.

\* 21 CFR 56.107(d): "Each IRB shall include at least one member whose primary concerns are in nonscientific areas... and at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person affiliated with the institution." There is no minimum requirement of seven members (A). Nonscientists must be represented but not a majority (B). Clergy are not mandated (C). The critical safeguard is inclusion of at least one unaffiliated member (D) to ensure independence.

Thus, the correct answer is D (At least one unaffiliated individual).

References:

21 CFR 56.107(d) (IRB membership requirements).

### NEW QUESTION # 72

A study coordinator is preparing an IRB submission for a Phase II oncology study. Which document must be included?

- A. Case report forms
- B. Record storage plan
- **C. Recruitment materials**
- D. List of potential subjects

**Answer: C**

Explanation:

\* ICH E6(R2) 3.1.2 & FDA Recruitment Guidance (1998): Recruitment materials must be reviewed by IRB to ensure no coercion or misleading claims.

\* CRFs and storage plans are sponsor/site tools, not IRB-reviewed documents.

References: ICH E6(R2) §3.1.2; FDA Recruitment Guidance, 1998.

### NEW QUESTION # 73

A research protocol requires patients to complete a patient reported outcome questionnaire in the sponsor's electronic data capture (EDC) system. What is the source data?

- A. A printout of the EDC record
- B. A printout of the electronic medical record
- **C. The EDC record**
- D. The electronic medical record

**Answer: C**

Explanation:

Source data are original records where data are first recorded.

\* ICH E6(R2) 1.51: Defines source data as "all information in original records and certified copies of original records of clinical

findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial." Since subjects directly enter responses into the EDC, the EDC record itself is the original source document. EMRs (B, C) and printouts (D) are secondary records.  
Correct answer: A (The EDC record).  
References:  
ICH E6(R2), §1.51 (Definition of source data).

## NEW QUESTION # 74

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