

# SOCRA CCRP Exam Certification Cost & CCRP Pdf Torrent

## CCRP SOCRA Exam Graded A+

- April 30 1996 - ANSWER ICH GCP Development Date
- Quality - ANSWER ICH Q
- Efficacy - ANSWER ICH E
- Safety - ANSWER ICH S
- Multidisciplinary - ANSWER ICH M
- guidance for industry, consolidated guidance - ANSWER ICH E 6
- Clinical Safety Data Management Definitions and Standards - ANSWER ICH E2A
- Safety pharmacology studies for human pharmaceuticals - ANSWER ICH S7A
- Electronic records, electronic signatures - ANSWER 21 CFR Part 11
- Informed Consent - ANSWER 21 CFR Part 50
- Financial Disclosures - ANSWER 21 CFR Part 54
- Institutional Review Board - ANSWER 21 CFR Part 56
- IND Application - ANSWER 21 CFR 312
- New Drug Application - ANSWER 21 CFR 314
- Investigational Device Exemption - ANSWER 21 CFR 812
- 21 CFR Part 814 - ANSWER pre market approval of medical devices
- 45 CFR Part 46 - ANSWER Federal Research
- Studies that investigate the potential undesirable PD effects of a substance on physiological functions in relation to exposure in the therapeutic range or above - ANSWER Safety Pharmacology Studies (Pre-Clinical)
  - 1) To identify undesirable PD properties of a substance that may have relevance to its human safety.
  - 2) To evaluate adverse PD and/or pathophysio effects of a substance observed in toxicology studies

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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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## Professional CCRP Exam Certification Cost & Perfect CCRP Pdf Torrent: Certified Clinical Research Professional (CCRP)

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## SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q106-Q111):

### NEW QUESTION # 106

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. Investigational product accountability forms
- 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 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 # 107

Why would a Phase IV study be conducted?

- A. Different marketing strategy
- B. Different dosage
- C. Different schedule of administration
- **D. Different off-label population**

**Answer: D**

Explanation:

Phase IV studies (post-marketing) examine real-world safety and effectiveness.

\* ICH E8(R1): Describes Phase IV as "studies performed after drug approval to delineate additional information including the drug's risks, benefits, and optimal use."

\* They often test drugs in new or broader populations beyond original approval.

While dosing and schedules are Phase I-III, Phase IV focuses on new patient populations or long-term outcomes.

References: ICH E8(R1).

### NEW QUESTION # 108

The reviewing IRB/IEC determined that a minimal risk sponsor-investigator study is exempt from IRB/IEC review. How often, if ever, is the sponsor-investigator required to submit a continuing review to the IRB/IEC?

- **A. There is no such requirement**
- B. Every year
- C. Every two years
- D. Exactly one time, at study closure

**Answer: A**

Explanation:

Minimal risk studies may qualify for exemption or expedited review under 45 CFR 46.101(b).

\* 45 CFR 46.109(f): "Unless an IRB determines otherwise, continuing review of research is not required for research eligible for expedited review and determined to involve no more than minimal risk."

\* ICH E6(R2) 3.1.4: Requires IRB review for clinical trials, but exemptions exist for minimal risk studies.

Therefore, once exempted, there is no requirement for continuing review, unless specifically required by the IRB. Submission at closure is optional depending on institutional policy but not a federal requirement.

Thus, the correct answer is D (No such requirement).

References:

45 CFR 46.109(f) (Exempt and expedited reviews).

### NEW QUESTION # 109

Which of the following statements about the investigator's brochure is correct?

- A. It consists of the instructions for the investigator to conduct the study
- B. It provides documents that permit the evaluation of the conduct of the study and the quality of the data
- C. It includes financial disclosure information from investigators
- **D. It contains a summary of the pharmacological and toxicological effects of the drug in animals, and to the extent known, in humans**

**Answer: D**

Explanation:

The Investigator's Brochure (IB) is a critical regulatory document designed to provide investigators with comprehensive knowledge about an investigational product.

\* ICH E6(R2) 7.1: Defines the IB as "a compilation of the clinical and nonclinical data on the investigational product(s) that are relevant to the study of the product(s) in human subjects."

\* ICH E6(R2) 7.2.2: Specifies the IB should contain a summary of pharmacological, toxicological, pharmacokinetic, and metabolic studies in animals, as well as results from previous human experience.

\* The purpose is to allow investigators to make risk-benefit assessments, support protocol design, and ensure subject safety.

Incorrect options:

\* A (instructions to conduct study) describes the protocol, not the IB.

\* C (financial disclosures) are required under 21 CFR 54, not part of the IB.

\* D refers to trial master file/essential documents, not the IB.

Therefore, the IB's defining function is to provide a scientific summary of preclinical and clinical data supporting safe human use.

References:

ICH E6(R2), §7.1, §7.2.2.

### NEW QUESTION # 110

According to 21 CFR Part 11, each electronic signature must be unique and:

- A. Transferable to family
- B. Identical to handwritten signature
- C. Reassignable after validation
- D. Cannot be reused or reassigned

**Answer: D**

Explanation:

\* 21 CFR 11.100(a): Requires that electronic signatures be "unique to one individual and shall not be reused or reassigned to anyone else."

\* This ensures accountability and audit trail integrity.

References: 21 CFR 11.100(a).

### NEW QUESTION # 111

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