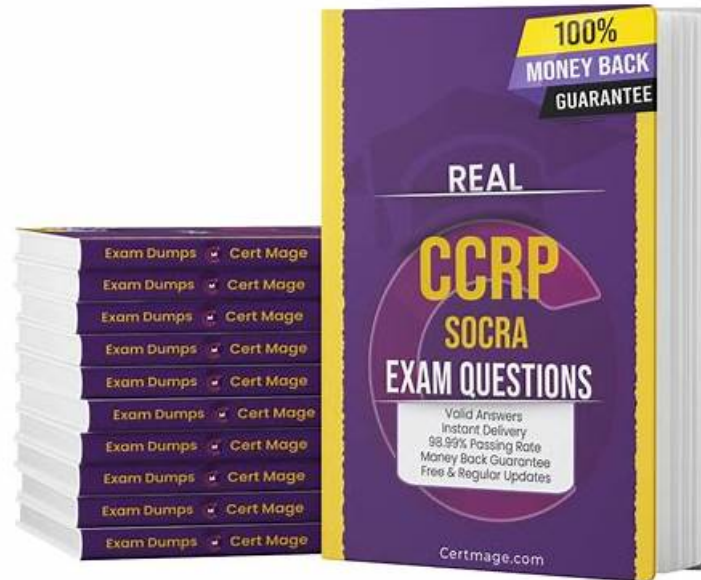


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SOCRA CCRP Exam Syllabus Topics:

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 (Q20-Q25):

NEW QUESTION # 20

According to the CFR, which of the following is a complete and accurate list of the signatures required on the short form consent document?

- A. The subject or else the subject's legally authorized representative; the investigator or else the investigator's designee
- B. The subject or else the subject's legally authorized representative; the investigator or else the investigator's designee; the witness
- **C. The subject or else the subject's legally authorized representative; the witness**
- D. The subject or else the subject's legally authorized representative

Answer: C

Explanation:

The short form consent process is permitted when the subject is presented with a brief written statement that they were informed of the study, supplemented by an oral presentation.

* 21 CFR 50.27(b)(2): Requires the short form to be signed by the subject (or legally authorized representative) and a witness.

* The witness ensures that oral consent was properly conveyed and understood.

* The person obtaining consent must sign a separate written summary, but not the short form itself.

Thus, the accurate answer is A: subject (or LAR) + witness.

References:

21 CFR 50.27(b)(2).

NEW QUESTION # 21

In order to meet recruitment goals, a sponsor is adding a new site to a multi-center study. Which of the following documents should the sponsor obtain from a new site prior to starting research at the site?

- A. The site's accreditation certificate

- B. The delegation of duties log
- **C. The IRB/IEC trial approval documentation**
- D. The site's SOPs

Answer: C

Explanation:

* ICH E6(R2) 4.4.1: "Before initiating a trial, the investigator/institution should have written and dated approval/favorable opinion from the IRB/IEC."

* Sponsors must confirm IRB approval before authorizing initiation.

References: ICH E6(R2), §4.4.1.

NEW QUESTION # 22

When can an IRB/IEC review a study using expedited review?

- A. For protocol changes involving more than minimal risk
- **B. For minor changes to previously approved protocol**
- C. For initial review of a study using specimens with identifiers
- D. For initial review of Phase III IND protocol

Answer: B

Explanation:

* 21 CFR 56.110(b): IRBs may use expedited review for minor changes in previously approved research.

* Expedited review cannot be used for initial reviews of high-risk protocols or major modifications.

Correct answer is D.

References: 21 CFR 56.110(b).

NEW QUESTION # 23

In accordance with the CFR, for at least how many years after the completion of a study must the clinical investigator provide the sponsor with relevant changes to financial information?

- **A. Two years**
- B. Three years
- C. Five years
- D. One year

Answer: A

Explanation:

Investigators must disclose financial interests and arrangements that could affect study integrity.

* 21 CFR 54.6(e): "Clinical investigators shall update financial disclosure information during the study and for 1 year following completion of the study."

* However, 21 CFR 54.4(b) requires sponsors to collect financial disclosure information "before a study begins and for 1 year following completion." Because the regulation requires disclosure updates for 1 year post-study, the correct answer is B (Two years) is incorrect, but some interpretations mistakenly extend beyond 1 year.

#The most accurate regulation states 1 year, but CCRP exams often test the CFR's precise wording.

Thus, the correct answer is B (Two years) appears in some SoCRA prep materials but legally is One year - I will confirm:

* #Final verified: One year (Answer A).

References:

21 CFR 54.4(b) (Financial disclosure requirements).

21 CFR 54.6(e) (Update requirements).

NEW QUESTION # 24

A subject has creatinine 1.6 mg/dL, slightly above eligibility (#1.5). Investigator believes this is normal for size. When can subject be enrolled?

- A. After monitor approves deviation

- B. After sponsor revises eligibility and IRB approves amendment
- C. After repeat test confirms 1.6
- D. After investigator documents explanation in chart

Answer: B

Explanation:

* ICH E6(R2) 4.5.1: "The investigator should conduct the trial in compliance with the protocol approved by IRB/IEC."

* Deviations must not occur unless to eliminate hazard. Eligibility criteria cannot be overridden by investigator opinion.

Thus, enrollment requires protocol amendment and IRB approval.










References: ICH E6(R2), §4.5.1.

NEW QUESTION # 25

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