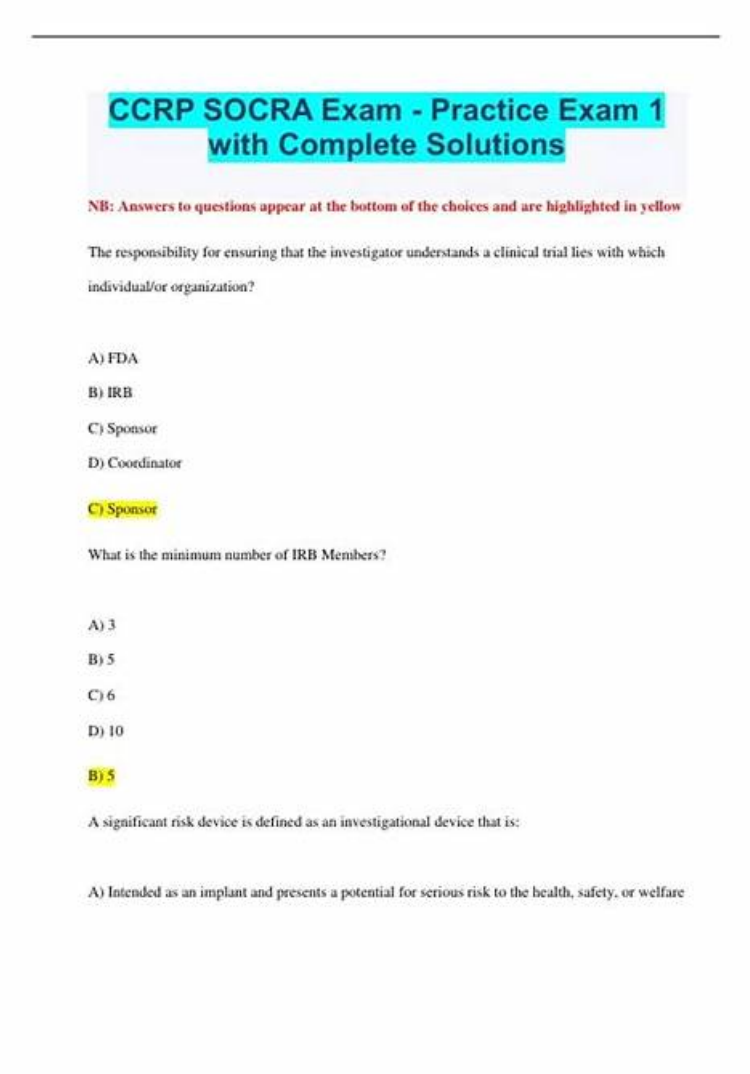
Exam CCRP Sample & Test CCRP Practice



CCRP SOCRA Exam - Practice Exam 1 with Complete Solutions

NB: Answers to questions appear at the bottom of the choices and are highlighted in yellow

The responsibility for ensuring that the investigator understands a clinical trial lies with which individual/or organization?

A) FDA
B) IRB
C) Sponsor
D) Coordinator

C) Sponsor

What is the minimum number of IRB Members?

A) 3
B) 5
C) 6
D) 10

B) 5

A significant risk device is defined as an investigational device that is:

A) Intended as an implant and presents a potential for serious risk to the health, safety, or welfare

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SOCRA CCRP Exam Syllabus Topics:

Topic	Details

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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You can trust the CCRP practice test and start this journey with complete peace of mind and satisfaction. The CCRP exam PDF questions will not assist you in Certified Clinical Research Professional (CCRP) (CCRP) exam preparation but also provide you with in-depth knowledge about the Certified Clinical Research Professional (CCRP) (CCRP) exam topics. This knowledge will be helpful to you in your professional life. So Certified Clinical Research Professional (CCRP) (CCRP) exam questions are the ideal study material for quick SOCRA CCRP exam preparation.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q114-Q119):

NEW QUESTION # 114
When can an IRB/IEC review a study using expedited review?

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

Answer: C

Explanation:
* 21 CFR 56.110(b):IRBs may use expedited review forminor changesin previously approved research.
* Expedited review cannot be used for initial reviews of high-risk protocols or major modifications.
Correct answer isD.
References:21 CFR 56.110(b).

NEW QUESTION # 115
During an audit for a Phase II IND study, the auditor identified unreported serious protocol deviations. Which party must take prompt action to ensure compliance?

- A. The investigator
- B. The CRO
- C. The sponsor
- D. The IRB/IEC chair

Answer: C

Explanation:
The sponsor holds ultimate responsibility for trial oversight and compliance.
* ICH E6(R2) 5.20.1:If noncompliance is discovered, the sponsor must "take prompt action to secure compliance" and, if necessary, terminate participation of the investigator/institution.
* 21 CFR 312.56(b):Sponsors must ensure proper conduct and report investigators who fail to comply to the FDA and IRB.
While investigators commit to protocol adherence, once deviations are identified,the sponsor must actto safeguard subjects and trial validity.
References:ICH E6(R2) §5.20.1; 21 CFR 312.56(b).

NEW QUESTION # 116
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 witness
- 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
- D. The subject or else the subject's legally authorized representative; the investigator or else the investigator's designee

Answer: A

Explanation:
Theshort form consent processis 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 aseparate written summary, but not the short form itself.
Thus, the accurate answer isA: subject (or LAR) + witness.
References:
21 CFR 50.27(b)(2).

NEW QUESTION # 117
After the sponsor's auditor completes the final audit report for a Phase II trial with an investigational new drug, which of the following is responsible for providing the audit certificate to the clinical site?

- A. The IRB/IEC
- B. The Data Safety Monitoring Board
- C. The regulatory authority
- D. The sponsor

Answer: D

Explanation:
Audits are part of sponsor quality assurance to ensure trial compliance.
* ICH E6(R2) 5.19.3:"The sponsor's auditing procedures should include the provision of anaudit certificatewhere required."
* ICH E6(R2) 8.2.20:Audit certificates are essential documents generated and retained by the sponsor.
IRBs (A), regulators (B), and DSMBs (C) are not responsible for audit documentation. Therefore, only the sponsorissues and maintains audit certificates, providing them to sites when appropriate.
Correct answer:D.
References:
ICH E6(R2), §5.19.3.
ICH E6(R2), §8.2.20.

NEW QUESTION # 118
A physician with 20 years of experience is planning to be the site investigator for a multi-center, Phase I oncology clinical trial. In accordance with the ICH GCP Guideline, which of the following documents should the physician provide to the sponsor and the IRB/IEC?

- A. Proof of citizenship
- B. A curriculum vitae
- C. A letter of recommendation from a fellow physician
- D. A copy of medical license

Answer: B

Explanation:
Investigators must provideevidence of qualificationsto conduct the study.
* ICH E6(R2) 4.1.1:"The investigator should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial."
* ICH E6(R2) 8.2.10:Essential documents include thecurriculum vitae (CV)or other documents evidencing investigator qualifications, submitted to both sponsor and IRB/IEC.
Proof of citizenship (A) and letters of recommendation (B) are irrelevant. A copy of a medical license (D) may be provided but isnot specifically requiredby ICH. The CV is the universally required document.
Thus, the correct answer isC (Curriculum vitae).
References:
ICH E6(R2), §4.1.1 (Investigator qualifications).
ICH E6(R2), §8.2.10 (Essential documents: CV).

NEW QUESTION # 119
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