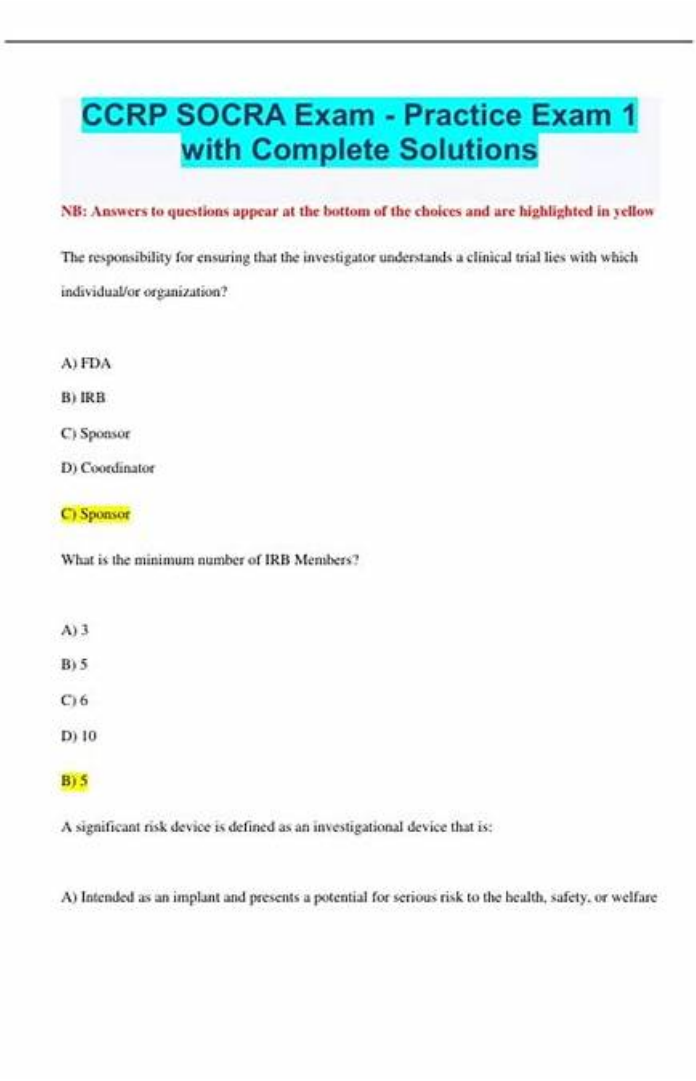
Exam SOCRA CCRP Bootcamp, Exam CCRP Questions



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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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q76-Q81):

NEW QUESTION # 76
Which of the following elements should NOT influence the investigator's ability to obtain endpoint data?

- A. Participant compliance
- B. Length of study follow-up
- C. Complexity of study
- D. Complexity of CRFs

Answer: D

Explanation:
* Endpoint data collection is based onprotocol designand subject compliance, not CRF formatting.
* ICH E6(R2) 4.9.0:Investigator responsible for data accuracy regardless of CRF complexity.
References:ICH E6(R2), §4.9.0.

NEW QUESTION # 77
According to the CFR, when children who are wards of the state are enrolled into a clinical trial, what is required?

- A. Each child must have a patient advocate
- B. The IRB/IEC must include a member who advocates for the children
- C. The investigator must represent the children
- D. Assenting children must self-represent

Answer: B

Explanation:
Children who are wards of the state receiveadditional protectionsin clinical research.
* 45 CFR 46.409(b):For research involving wards, "the IRB shall require appointment of an advocate for each child, in addition to any guardian or other advocate who would ordinarily be provided."
* The advocate must have background and experience to act in the child's best interest and cannot be associated with the research.
Thus, anIRB-appointed advocateis mandatory to ensure independent representation of the ward's rights.
References:45 CFR 46.409(b).

NEW QUESTION # 78
Which of the following adverse events occurring during a study of an investigational new drug would require the sponsor to notify the FDA as soon as possible but in no case later than seven calendar days after the initial receipt of the information?

- A. Aplastic anemia requiring hospitalization, mentioned in the investigator's brochure
- B. Death due to disease progression, mentioned in the investigator's brochure
- C. An infection not related to the investigational drug requiring hospitalization for antibiotic therapy
- D. Death as a result of arrhythmias (irregular heart rhythm), not mentioned in the investigator's brochure and thought to be related to the use of the drug

Answer: D

Explanation:
Sponsors must reportserious, unexpected, and suspected adverse reactions (SUSARs)to the FDA.
* 21 CFR 312.32(c)(2):"Any adverse experience associated with the use of the drug that is bothserious and unexpectedshall be reported...as soon as possible but no later than 7 calendar daysafter the sponsor's initial receipt of the information, if it is fatal or life-threatening."
* ICH E2A 4.2:Requires expedited reporting oflife-threatening or fatal SUSARswithin 7 days.
Among the options, only (C) -death from arrhythmias not previously identified in the Investigator's Brochure and suspected to be drug-related- meets the definition of a SUSAR requiring7-day expedited reporting. Events already listed in the IB (A, D) or unrelated to the drug (B) do not trigger expedited reporting.
Thus, the correct answer isC.
References:
21 CFR 312.32(c)(2) (Expedited safety reporting).
ICH E2A, §4.2 (Expedited reporting of fatal/life-threatening adverse events).

NEW QUESTION # 79
A clinical investigator is planning to conduct a quality of life medical device study in the United States. The study has been designed to comply with the approved indication for use of the device. In this situation, who must approve the investigator's proposed patient recruitment materials?

- A. An IRB/IEC
- B. A scientific review board
- C. The FDA
- D. The Office for Human Research Protections (OHRP)

Answer: A

Explanation:
Recruitment materials must be reviewed to protect subjects from misleading or coercive messaging.
* 21 CFR 56.111(a)(3):IRBs must ensure equitable subject selection.
* ICH E6(R2) 3.1.2:IRBs safeguard rights, safety, and well-being, including review of recruitment strategies.
FDA and OHRP do not approve recruitment materials; responsibility lies withIRB/IEC.
References:21 CFR 56.111(a)(3); ICH E6(R2) §3.1.2.

NEW QUESTION # 80
Which of the following entities, if any, must provide an approval before an investigator may enroll subjects in a quality-of-life research questionnaire study?

- A. The IRB/IEC
- B. The Department of Health and Human Services
- C. No approvals are necessary if no pharmaceutical drugs are involved
- D. The FDA or another regulatory authority

Answer: A

Explanation:
Even if a study does not involve drugs, devices, or biologics, it still involveshuman subjectsand therefore requiresethical review by an IRB/IEC.
* 45 CFR 46.109(a):"An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy."
* ICH E6(R2) 3.1.2:"The IRB/IEC should safeguard the rights, safety, and well-being of all trial subjects." Quality-of-life (QOL) studies may involve surveys, interviews, or questionnaires, but since they involve human participants, they are subject to human research protection regulations. FDA involvement is not required unless drugs or devices are tested. Similarly, HHS approval is not required unless the study is federally funded.
Thus, the correct answer isC (The IRB/IEC).
References:
45 CFR 46.109(a) (IRB review of research).
ICH E6(R2), §3.1.2 (IRB/IEC role in subject protection).

NEW QUESTION # 81
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