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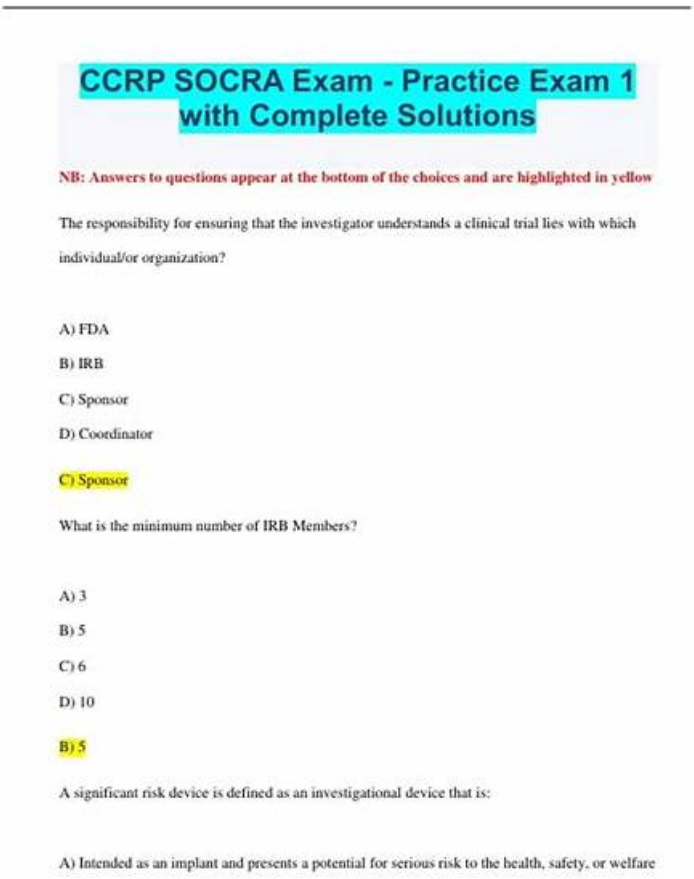

CCRP SOCRA Exam - Practice Exam 1 with Complete Solutions

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 (Q55-Q60):

NEW QUESTION # 55
A sponsor-investigator implemented a protocol deviation in a device trial to eliminate an immediate hazard.
Before applying this change to all subjects, what must occur?

- A. Document change in study file
- B. Train sub-investigators
- C. Inform all subjects
- D. Obtain IRB/IEC approval

Answer: D

Explanation:
* 21 CFR 812.35(a)(2):Allows deviation without prior approval only to eliminate immediate hazards.
* Before applying broadly,IRB approvalmust be obtained.
References:21 CFR 812.35(a)(2).

NEW QUESTION # 56
A study coordinator is preparing an IRB submission for a Phase II oncology study. Which document must be included?

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

Answer: A

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 # 57
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 sponsor revises eligibility and IRB approves amendment
- B. After investigator documents explanation in chart
- C. After monitor approves deviation
- D. After repeat test confirms 1.6

Answer: A

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 # 58
During an IND study closeout, a monitor discovered remaining investigational product. Which procedures must be followed for disposition?

- A. IRB/IEC's procedures
- B. Dispensing pharmacy's procedures
- C. Regulatory authority's procedures
- D. Sponsor's procedures

Answer: D

Explanation:
* ICH E6(R2) 5.13.3:The sponsor is responsible for the supply, storage, and final disposition of investigational product.
* 21 CFR 312.59:Sponsors must assure return or proper disposition of unused supplies.
* Sites must followsponsor's written proceduresfor reconciliation, return, or destruction, not IRB or pharmacy processes.
References:ICH E6(R2) §5.13.3; 21 CFR 312.59.

NEW QUESTION # 59
Which of the following statements about the initial IND application submission by a sponsor to the U.S. Food and Drug Administration is correct?

- A. It includes a disclosure of the financial interests and arrangements of clinical investigators
- B. It includes the rationale for human testing and a description of the general investigational plan
- C. It is an application to export the investigational drug
- D. It is an application for the sponsor to sell the drug for profit

Answer: B

Explanation:
AnInvestigational New Drug (IND) applicationprovides FDA with data to justify human testing.
* 21 CFR 312.23(a)(3):The IND must contain "a description of the general investigational plan, including the rationale for the drug or the research study."
* The IND also includes preclinical safety data, manufacturing details, investigator qualifications, and study protocols.
Financial disclosures (D) are reported separately under21 CFR Part 54, not as part of the initial IND. Export applications (A) are covered under21 CFR 312 Subpart E. Profit sales (C) are not permitted under INDs.
Thus, the correct answer isB (Rationale and plan for human testing).
References:
21 CFR 312.23(a)(3) (IND contents).
21 CFR 312.20 (General IND requirements).

NEW QUESTION # 60
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