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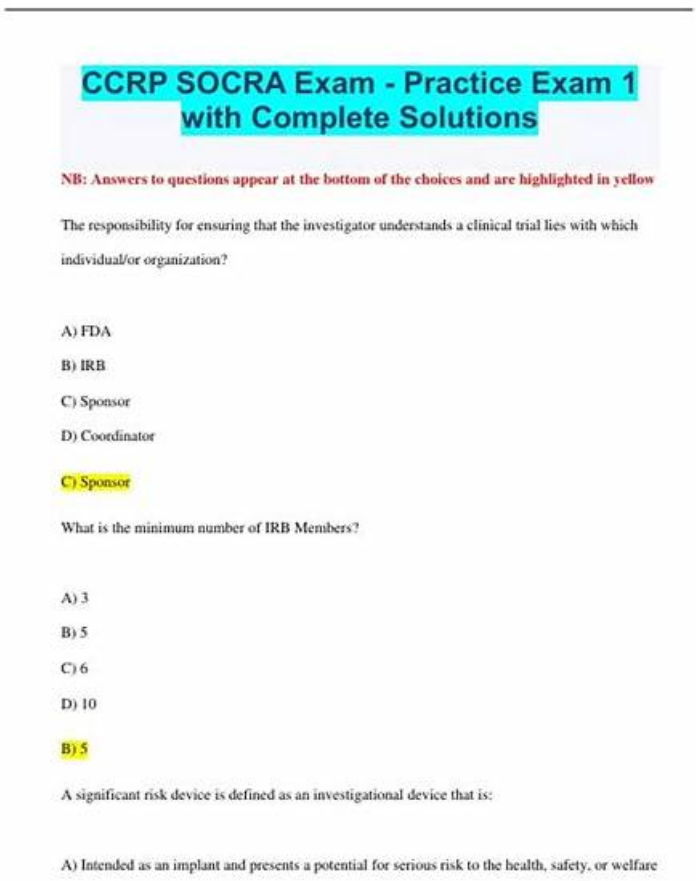

CCRP SOCRA Exam - Practice Exam 1 with Complete Solutions

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 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	• 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.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q126-Q131):

NEW QUESTION # 126
The sponsor of a multi-institutional clinical trial provided a site with information regarding a newly identified unanticipated adverse event attributed to study drug administration. The site's investigator has a subject actively receiving this study drug. Which of the following is the site investigator's responsibility to the subject?

- A. To discontinue the subject's study drug
- B. To provide the subject with information regarding the significant new findings
- C. To submit this safety update to the regulatory authority
- D. To give the subject's contact information to the sponsor in order to allow the sponsor to contact the subject

Answer: B

Explanation:
Investigators are obligated to inform subjects ofnew informationthat may affect their willingness to continue.
* ICH E6(R2) 4.8.2:"If new information becomes available that may be relevant to a subject's willingness to continue participation, the informed consent document should be revised, and the subject should be informed in a timely manner."
* 21 CFR 50.25(b)(5):Consent must include a statement that "significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided." Thus, the investigator mustcommunicate new risk information to the subject.
Discontinuation (A) may not be warranted unless medically indicated. Reporting to FDA (B) is the sponsor's role. Sharing subject contact with sponsor (D) would violate confidentiality.
Correct answer:C.
References:
ICH E6(R2), §4.8.2.
21 CFR 50.25(b)(5).

NEW QUESTION # 127
A company's CEO wants to commercially promote a device under an IDE study. This plan:

- A. Requires IDE approval
- B. Requires IRB/IEC approval
- C. Would violate FDA regulations
- D. Requires a large advertising budget

Answer: C

Explanation:
* 21 CFR 812.7:Prohibits promotion of investigational devices or claiming safety/effectiveness until FDA approval is granted.
* Investigational devices may only be used in clinical trials, not marketed.
Thus, promotion during an IDE study is anFDA violation.
References:21 CFR 812.7.

NEW QUESTION # 128
After the completion of a Phase II IND study closeout monitoring visit, which of the following parties is responsible for maintaining the closeout monitoring report?

- A. The sponsor
- B. The IRB/IEC
- C. The study coordinator
- D. The investigator

Answer: A

Explanation:
Monitoring reports are sponsor-controlled documents.
* ICH E6(R2) 5.18.6:"The monitor should submit a written report to the sponsor after each trial-site visit... The sponsor should review and follow up on the monitoring report."
* ICH E6(R2) 8.1 & 8.2.22:Monitoring visit reports are essential documents maintained by the sponsor.
Investigators are not required to retain monitoring reports; they maintain site regulatory binders and subject records. The study coordinator assists investigators, but does not hold sponsor-owned reports. IRBs also do not receive sponsor monitoring reports.
Thus, the correct answer isB (The sponsor).
References:
ICH E6(R2), §5.18.6 (Monitoring reports).
ICH E6(R2), §8.2.22 (Essential documents: monitoring visit reports).

NEW QUESTION # 129
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 Data Safety Monitoring Board
- B. The sponsor
- C. The IRB/IEC
- D. The regulatory authority

Answer: B

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 # 130
In accordance with ICH, which of the following is an acceptable protocol review frequency for an IRB?

- A. 6 months
- B. 36 months
- C. 24 months
- D. 12 months

Answer: D

Explanation:
IRBs must review protocols at least annually to ensure ongoing subject protection.
* 21 CFR 56.109(f):"An IRB shall conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year."
* ICH E6(R2) 3.1.4:"The IRB/IEC should conduct continuing review of each ongoing trial at intervals appropriate to the degree of risk, but at least once per year." This establishes12 monthsas the minimum required interval. More frequent reviews (e.g., 6 months) may occur for higher-risk studies, but longer intervals (24-36 months) are not permitted.
Correct answer:B (12 months).
References:
21 CFR 56.109(f).
ICH E6(R2), §3.1.4.

NEW QUESTION # 131
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