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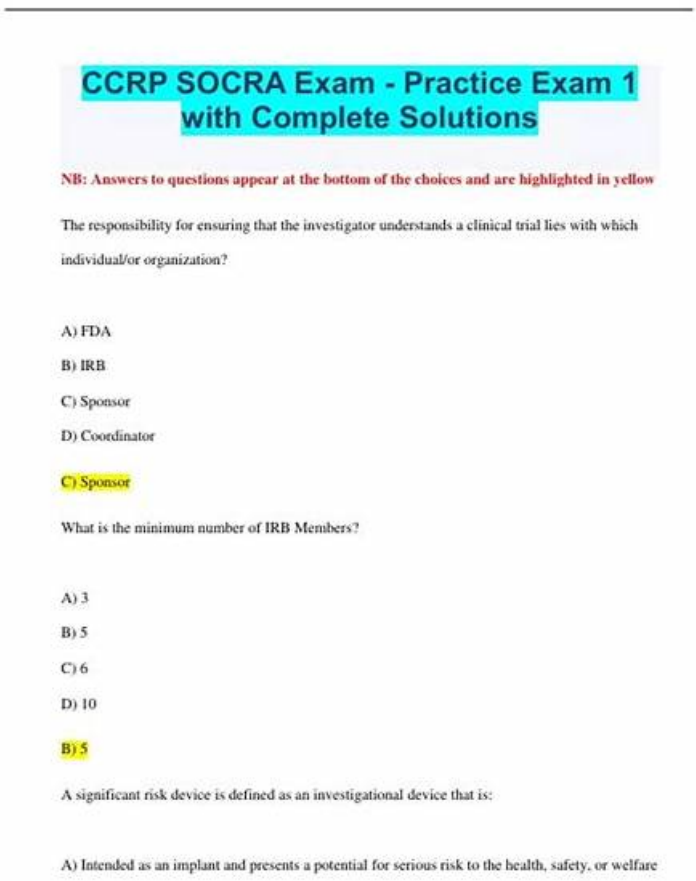

CCRP SOCRA Exam - Practice Exam 1 with Complete Solutions

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.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q45-Q50):

NEW QUESTION # 45
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 sponsor
- B. The regulatory authority
- C. The IRB/IEC
- D. The Data Safety Monitoring Board

Answer: A

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 # 46
Which of the following is one of the responsibilities of an investigator?

- A. Selecting qualified monitors on the basis of training, experience, and expertise
- B. Updating the investigator brochure with new safety information
- C. Maintaining accurate and current case histories of study subjects
- D. Participating in the IRB/IEC voting process for approval of their protocol

Answer: C

Explanation:
Investigators are required to maintain accurate subject records, often referred to ascase histories.
* 21 CFR 312.62(b):"An investigator shall prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation."
* ICH E6(R2) 4.9.0:Reinforces that investigators are responsible for recording, handling, and storing clinical trial data.
Incorrect options:
* B: Investigators may present protocols but cannot vote on IRB approval.
* C: Sponsor responsibility (ICH E6 §5.18).
* D: Sponsors are responsible for IB updates (ICH E6 §7.3.1).
Correct answer:A.
References:
21 CFR 312.62(b).
ICH E6(R2), §4.9.0.

NEW QUESTION # 47
In an IND study, the specified dosage of an investigational product is 2 mg twice a day for 10 days. The product is available in 1 mg tablets. The subject was given 45 tablets and was instructed to take 2 mg of the product twice a day for 10 days. How many tablets should the subject have after the 10 days?

- A. 0
- B. 1
- C. 2
- D. 3

Answer: A

Explanation:
This question tests drug accountability and dosing calculation, which is central to ICH E6(R2) 4.6 (Investigational product management). Subjects must receive the correct supply and any discrepancy must be reconciled.
The prescribed regimen is 2 mg twice daily = 4 mg per day. With 1 mg tablets, this equals 4 tablets daily.
Over 10 days, the subject should consume 40 tablets (4 × 10 = 40). Since 45 tablets were dispensed, the subject should have 5 tablets remaining after 10 days.
Accurate accountability ensures trial integrity and subject safety. Investigators are responsible for maintaining investigational product (IP) records, including dispensing, usage, and returns. According to ICH:
4.6.3: "The investigator/institution should maintain records of the product's delivery to the trial site, the inventory, the use by each subject, and the return to the sponsor or alternative disposition."
4.6.5: "The investigator should ensure that investigational products are used only in accordance with the approved protocol." Thus, the correct answer is C (5 tablets remain). This reflects proper dosing compliance and highlights the importance of meticulous IP tracking in clinical trials.
References:
ICH E6(R2), §4.6 (Investigational Product(s)).

NEW QUESTION # 48
In accordance with 45 CFR 46, in addition to the Office for Human Research Protections (OHRP), a suspension of IRB/IEC approval must be reported to which of the following?

- A. The appropriate institutional officials
- B. The local hospital's medical director
- C. The local hospital's bioethics committee

- D. The Scientific Review Committee

Answer: A

Explanation:
If IRB/IEC approval is suspended or terminated, reporting is required to protect oversight and accountability.
* 45 CFR 46.113:"An IRB shall notify theinstitutional officials, the department or agency head, and OHRP(when applicable) of any suspension or termination of IRB approval." This ensures transparency and institutional responsibility for compliance. Internal hospital committees or directors (A, C, D) are not mandated reporting entities.
Thus, the correct answer isB (Appropriate institutional officials).
References:
45 CFR 46.113 (Suspension or termination of IRB approval).

NEW QUESTION # 49
Before approving a research protocol, an IRB/IEC must determine compliance with which of the following requirements?

- A. A plan for the publication of study results is in place
- B. The investigator has adequate access to patients eligible for the trial
- C. The selection of subjects is equitable
- D. The sponsor is qualified to provide oversight of the trial

Answer: C

Explanation:
IRB/IEC review focuses onethical protection of human subjects. Equitable subject selection is a cornerstone principle.
* 45 CFR 46.111(a)(3):"In order to approve research... the IRB shall determine that:Selection of subjects is equitable."
* ICH E6(R2) 3.1.2:"The IRB/IEC should safeguard the rights, safety, and well-being of all trial subjects... with particular attention to trials that may include vulnerable subjects." Publication plans (A) are not required by IRBs. Access to patients (C) and sponsor qualifications (D) are evaluated by sponsors, not IRBs. The IRB's role is ensuring fairness, minimizing coercion, and protecting vulnerable populations.
Thus, the correct answer isB (The selection of subjects is equitable).
References:
45 CFR 46.111(a)(3) (Equitable subject selection).
ICH E6(R2), §3.1.2 (IRB/IEC role).

NEW QUESTION # 50
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