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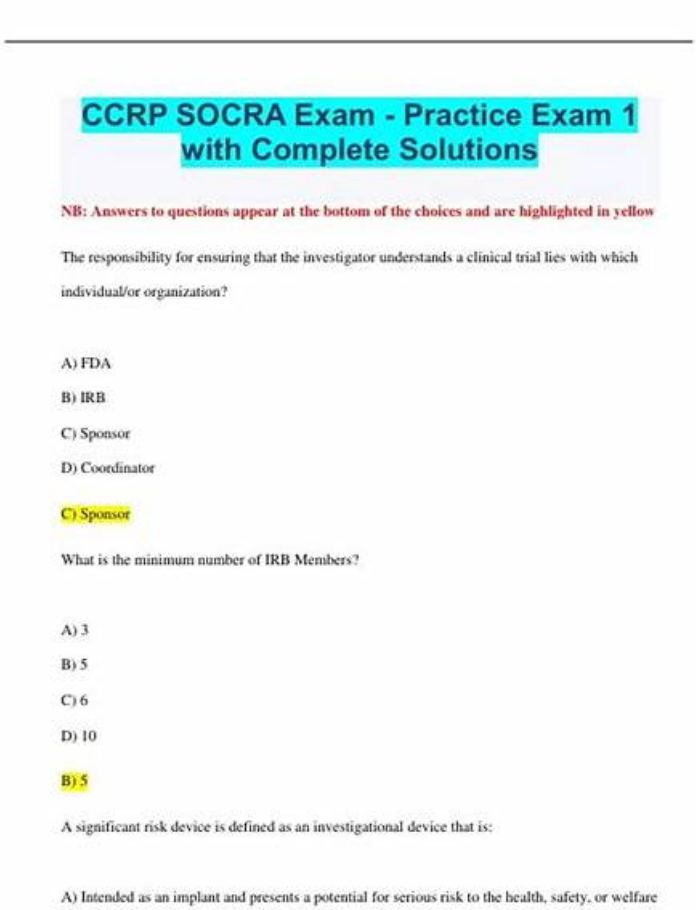

CCRP SOCRA Exam - Practice Exam 1 with Complete Solutions

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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time.

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 (Q35-Q40):

NEW QUESTION # 35
A clinical investigator terminated a Phase IV drug study. In accordance with the ICH GCP Guidelines, which of the following documents should the clinical investigator maintain?

- A. The audit certificate
- B. The final trial closeout monitoring report
- C. The master randomization list
- D. The completed subject identification code list

Answer: D

Explanation:
Upon study closure, investigators must maintain documentation that allows subject data to be linked back if necessary. TheSubject Identification Code Listis a key essential document for ensuring traceability while maintaining confidentiality.
* ICH E6(R2) 8.3.21:"Subject Identification Code List - A list of all subjects randomized to trial numbers, allowing investigator to identify each subject in case follow-up is required. This list should be kept in a confidential manner and retained for the maximum retention period."
* ICH E6(R2) 8.4:Essential documents for investigators include items needed for subject identification, protocol compliance, and trial closure.
Other listed documents (randomization list, monitoring report, audit certificate) are maintained by the sponsor, not the investigator. Thesubject code listensures that in the event of a safety issue, regulatory authority queries, or subject withdrawal, the investigator can trace back records.
Thus, the correct answer isB (Completed Subject Identification Code List).
References:
ICH E6(R2), §8.3.21 (Essential documents: Subject identification code list).
ICH E6(R2), §8.4 (Essential documents for trial closure).

NEW QUESTION # 36
A clinical investigator is developing the assent procedure for the enrollment of children into a new pediatric clinical trial. The ages of the children are described in the IRB/IEC submission. A description of which of the following must also be included in the submission?

- A. The pediatrician (primary care provider notification process)
- B. The economic status of the children
- C. The psychological status of the children
- D. The physiological status of the children

Answer: C

Explanation:
Children are avulnerable populationrequiring additional protections.
* 45 CFR 46.408(a):Requires "adequate provisions for soliciting the assent of the children, when in the judgment of the IRB, the children are capable of providing assent."
* 45 CFR 46.402:Defines "assent" as a child's affirmative agreement to participate.
* IRBs must consider theage, maturity, and psychological stateof the children when determining assent capability.
Economic status (B) is irrelevant to assent. Physiological status (C) pertains to eligibility, not assent. Provider notification (D) may be local practice but not required by regulation.
Correct answer:A (Psychological status).
References:
45 CFR 46.402-408.

NEW QUESTION # 37
Protecting prisoners' rights to voluntarily participate in research is an example of which Belmont principle?

- A. Justice
- B. Respect for Persons
- C. Beneficence
- D. Dignity

Answer: B

Explanation:
* Belmont Report:"Respect for Persons" incorporates two ethical convictions: treating individuals as autonomous agents and protecting those with diminished autonomy (e.g., prisoners).
* Prisoners require special safeguards because of restricted liberty and potential coercion.
References:Belmont Report (1979).

NEW QUESTION # 38
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: D

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 # 39
Which of the following is one of the responsibilities of an investigator?

- A. Updating the investigator brochure with new safety information
- B. Selecting qualified monitors on the basis of training, experience, and expertise
- 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 # 40
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