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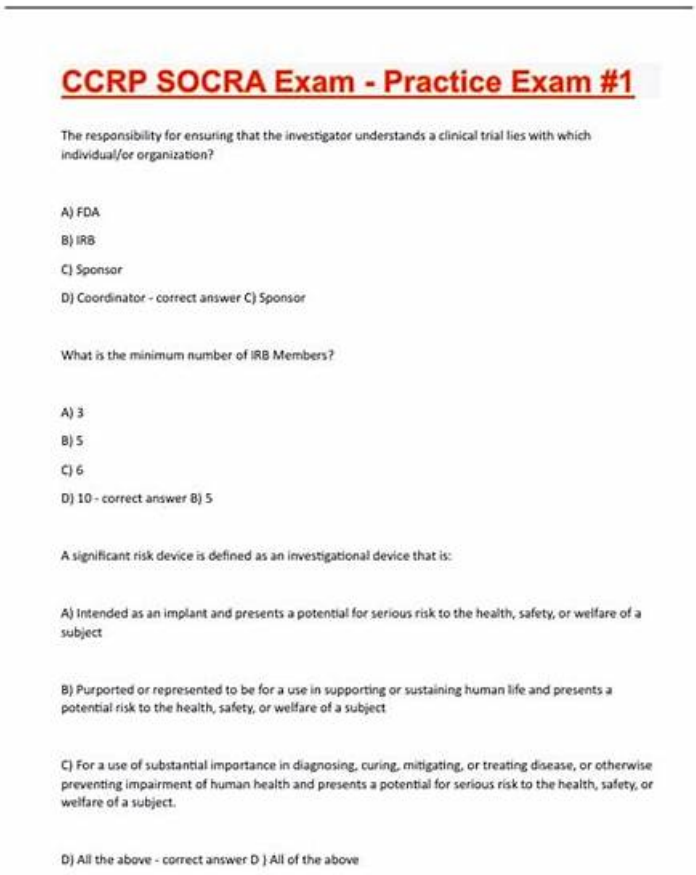

CCRP SOCRA Exam - Practice Exam #1

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 - correct answer C) Sponsor

What is the minimum number of IRB Members?

A) 3

B) 5

C) 6

D) 10 - correct answer 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 of a subject

B) Purported or represented to be for a use in supporting or sustaining human life and presents a potential risk to the health, safety, or welfare of a subject

C) For a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject.

D) All the above - correct answer D) All of the above

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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 (Q43-Q48):

NEW QUESTION # 43
In accordance with the CFR, which body must determine that a study meets the criteria for minimal risk?

- A. The medical monitor
- B. A data safety monitoring board
- C. The reviewing IRB/IEC
- D. The clinical investigator

Answer: C

Explanation:
Minimal risk determination is a regulatory function of the IRB/IEC.
* 45 CFR 46.102(j):Defines minimal risk as harm or discomfort not greater than those ordinarily encountered in daily life.
* 45 CFR 46.109(a):The IRB has authority to approve, require modifications, or disapprove research, including assessment ofrisk level.
* Investigators may propose a study as minimal risk, but only theIRB/IEC can formally classify it.
This ensures independent, unbiased evaluation of risk, protecting participants from investigator or sponsor bias.
References:45 CFR 46.102(j), 46.109(a).

NEW QUESTION # 44
Which of the following would be considered an addendum to an investigator's brochure for an unapproved Investigational Product?

- A. Product monograph updates
- B. Revisions to the risk section of the informed consent form
- C. A Suspected Unexpected Serious Adverse Reaction (SUSAR) report
- D. A site-specific SAE report

Answer: C

Explanation:
The IB must be updatedas new significant safety information emerges.
* ICH E6(R2) 7.3:"The sponsor should revise the IB as soon as new, significant information becomes available."
* ICH E2A:Requires sponsors to reportSuspected Unexpected Serious Adverse Reactions (SUSARs) in expedited reports and include them inIB updates or addenda.
A SUSAR report (B) represents new, unexpected, and serious safety information not previously documented, and therefore warrants inclusion as anIB addendumuntil the IB is formally updated.
Revised consent forms (A) are submitted to IRBs, not IBs. Site-specific SAE reports (C) remain at site /sponsor level, not in the IB. Product monograph updates (D) apply to approved products, not investigational ones.
Thus, the correct answer isB (SUSAR report).
References:
ICH E6(R2), §7.3 (Updating the Investigator's Brochure).
ICH E2A (Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

NEW QUESTION # 45
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 investigator
- C. The study coordinator
- D. The IRB/IEC

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 # 46
A revised protocol added genomic testing to banked tissue samples. Before shipping samples, what must the site do?

- A. Ship under dangerous goods requirements
- B. Notify enrolled subjects
- C. Execute material transfer agreement
- D. Obtain IRB/IEC approval for revised protocol and ICF

Answer: D

Explanation:
* 21 CFR 56.109(a):IRB must review and approve any protocol amendments before implementation.

* ICH E6(R2) 4.5.2:Changes affecting subjects (e.g., genomic testing) require IRB/IEC approval and updated consent.
Thus, site must first obtainIRB approval for revised protocol and ICF.
References:21 CFR 56.109(a); ICH E6(R2) §4.5.2.

NEW QUESTION # 47
A Phase I clinical trial is initiating. Who is responsible for ensuring that site staff are adequately informed about trial duties?

- A. Clinical investigator
- B. Program manager
- C. IRB/IEC
- D. Sponsor

Answer: A

Explanation:
* ICH E6(R2) 4.2.4:"The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, investigational product, and trial-related duties."This responsibility cannot be delegated to sponsor or IRB.
References:ICH E6(R2), §4.2.4.

NEW QUESTION # 48
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