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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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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 (Q118-Q123):

NEW QUESTION # 118

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

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

Answer: D

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 # 119

Which case history documents must be at both sponsor and site?

- A. Study visit notes
- B. Medical records
- **C. Case report forms (CRFs)**
- D. Signed informed consent forms

Answer: C

Explanation:

* ICH E6(R2) 1.11: CRFs are documents used to record protocol-required data reported to sponsor.

* Sites keep originals; sponsor retains copies. Consent forms and medical records stay at site only.

References:ICH E6(R2), §1.11.

NEW QUESTION # 120

In order to meet recruitment goals, a sponsor is adding a new site to a multi-center study. Which of the following documents should the sponsor obtain from a new site prior to starting research at the site?

- A. The delegation of duties log
- B. The site's accreditation certificate
- C. The IRB/IEC trial approval documentation
- D. The site's SOPs

Answer: C

Explanation:

* ICH E6(R2) 4.4.1:"Before initiating a trial, the investigator/institution should have written and dated approval/favorable opinion from the IRB/IEC."

* Sponsors must confirm IRB approval before authorizing initiation.

References:ICH E6(R2), §4.4.1.

NEW QUESTION # 121

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 IRB/IEC
- C. The regulatory authority
- D. The sponsor

Answer: D

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 an audit certificate where 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 sponsor issues 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 # 122

A subject enrolled in a drug clinical trial has withdrawn from the study. In accordance with ICH GCP, which of the following documents should be consulted to determine whether the participant should be replaced?

- A. The informed consent document
- B. The Investigator's Brochure
- C. The data safety monitoring plan
- D. The protocol

Answer: D

Explanation:

The protocol governs all trial conduct, including whether subjects should be replaced when they withdraw.

* ICH E6(R2) 6.0:The protocol must contain "detailed information on trial design, methodology, statistical considerations, and the organization of the trial."

* ICH E6(R2) 6.9.2:The section on "Subject withdrawal or discontinuation" specifies "whether and under what conditions subjects may be replaced." Other documents serve different functions: the DSM plan (A) manages safety oversight, the IB (C) summarizes

