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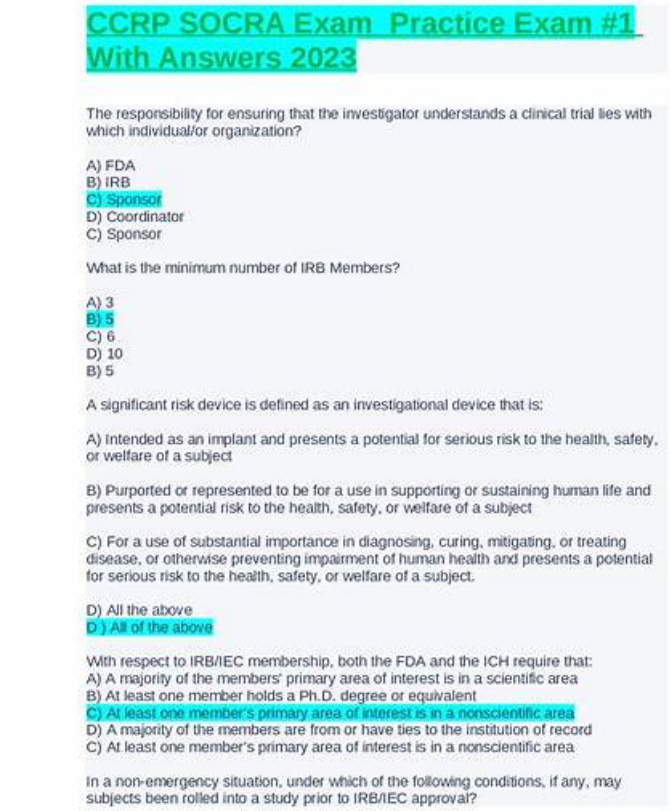

CCRP SOCRA Exam Practice Exam #1 With Answers 2023

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 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
D) All of the above

With respect to IRB/IEC membership, both the FDA and the ICH require that:
A) A majority of the members' primary area of interest is in a scientific area
B) At least one member holds a Ph.D. degree or equivalent
C) At least one member's primary area of interest is in a nonscientific area
D) A majority of the members are from or have ties to the institution of record
C) At least one member's primary area of interest is in a nonscientific area

In a non-emergency situation, under which of the following conditions, if any, may subjects been rolled into a study prior to IRB/IEC approval?

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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 CCRP Practice Questions

As is known to us, getting the newest information is very important for all people to pass the exam and get the certification in the shortest time. In order to help all customers gain the newest information about the CCRP exam, the experts and professors from our company designed the best Certified Clinical Research Professional (CCRP) test guide. The experts will update the system every day. If there is new information about the exam, you will receive an email about the newest information about the CCRP learning dumps. We can promise that you will never miss the important information about the exam.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q97-Q102):

NEW QUESTION # 97
In a Phase III cardiovascular trial, who is responsible for ongoing clinical trial safety evaluation?

- A. FDA
- B. Sponsor
- C. Pharmacist
- D. IRB/IEC

Answer: B

Explanation:
* ICH E6(R2) 5.16:Sponsors must implement ongoing safety evaluation, including expedited and periodic reporting.FDA and IRB review but do not conduct active monitoring.
References:ICH E6(R2), §5.16.

NEW QUESTION # 98
A sponsor received a report from an investigator regarding the investigator's use of an investigational device without having obtained informed consent. The sponsor must submit a copy of the report to the FDA within:

- A. 5 working days

- B. 30 working days
- C. 10 working days
- D. 1 day

Answer: A

Explanation:
Informed consent is a fundamental ethical requirement. If it is violated in a device trial, the FDA requires rapid reporting.
* 21 CFR 812.150(b)(5):States that a sponsor shall submit to FDA "any report of use of a device without obtaining informed consent, within5 working daysafter the sponsor first receives notice of such use."
* This expedited reporting ensures FDA oversight of serious violations and protection of human subjects.
Incorrect options:
* A (1 day) is overly strict and not codified.
* C (10 days) and D (30 days) are too delayed to meet regulatory intent of immediate oversight.
Thus, the correct timeline iswithin 5 working days.
References:
21 CFR 812.150(b)(5).

NEW QUESTION # 99
Which of the following is one of the responsibilities of an investigator who is NOT a sponsor?

- A. Ensuring proper monitoring of an investigation at all investigational sites
- B. Reporting serious adverse events to the applicable regulatory agency
- C. Maintaining control of the investigational product
- D. Ensuring that all participating investigators are promptly informed of significant new adverse events

Answer: C

Explanation:
For non-sponsor investigators, responsibilities are limited tosite-level conduct and product accountability.
* ICH E6(R2) 4.6.1:"Responsibility for investigational product(s) accountability at the trial site rests with the investigator/institution."
* 21 CFR 312.61:Requires the investigator to administer investigational drugs only to subjects under their supervision and maintain control.
Other responsibilities listed belong tosponsors:
* A: Reporting SAEs to FDA is a sponsor duty (investigators report to sponsor, not directly to FDA).
* B: Monitoring at all sites is a sponsor responsibility.
* C: Disseminating safety updates is a sponsor's role.
Correct answer:D (Maintaining control of IP).
References:
ICH E6(R2), §4.6.1.
21 CFR 312.61.

NEW QUESTION # 100
The sponsor discontinued the clinical development of an investigational product. In accordance with the ICH GCP Guidance, at least how long should the sponsor maintain all sponsor-specific essential documents?

- A. 2 years
- B. 5 years
- C. 3 years
- D. 15 years

Answer: A

Explanation:
Retention of essential documents ensures accountability and inspection readiness.
* ICH E6(R2) 5.5.12 & 8.1:Sponsors should retain essential documents "until at least2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applicationsor at least 2 years after formal discontinuation of clinical development of the investigational product." This standard balances subject protection with practical recordkeeping. Longer durations (B-D) may apply under institutional or national rules, but ICH establishes2 years minimum.

Correct answer:A (2 years).
References:
ICH E6(R2), §5.5.12, §8.1.

NEW QUESTION # 101
A company's CEO wants to commercially promote a device under an IDE study. This plan:

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

Answer: A

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 # 102
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