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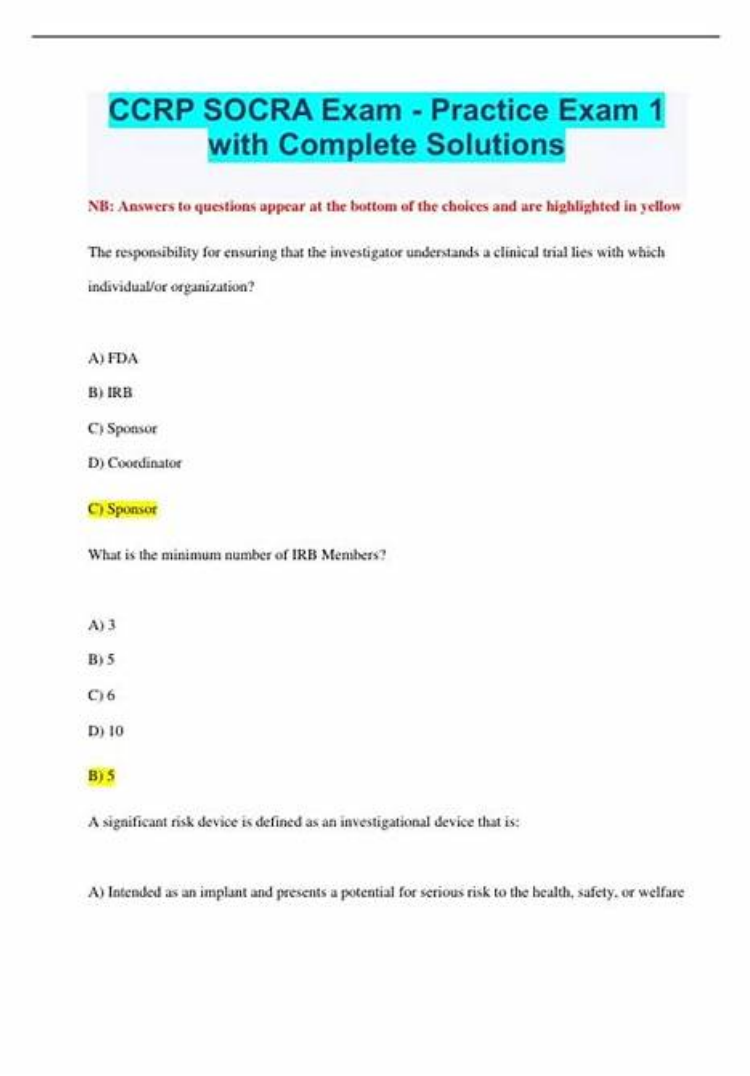

CCRP SOCRA Exam - Practice Exam 1 with Complete Solutions

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.

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q42-Q47):

NEW QUESTION # 42
A sponsor-investigator implemented a protocol deviation in a device trial to eliminate an immediate hazard.
Before applying this change to all subjects, what must occur?

- A. Inform all subjects
- B. Obtain IRB/IEC approval
- C. Train sub-investigators
- D. Document change in study file

Answer: B

Explanation:
* 21 CFR 812.35(a)(2):Allows deviation without prior approval only to eliminate immediate hazards.
* Before applying broadly,IRB approvalmust be obtained.
References:21 CFR 812.35(a)(2).

NEW QUESTION # 43
A research protocol requires patients to complete a patient reported outcome questionnaire in the sponsor's electronic data capture (EDC) system. What is the source data?

- A. The EDC record
- B. A printout of the electronic medical record
- C. The electronic medical record
- D. A printout of the EDC record

Answer: A

Explanation:
Source data areoriginal records where data are first recorded.
* ICH E6(R2) 1.51:Defines source data as "all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial." Since subjects directly enter responses into the EDC, theEDC record itself is the original source document.
EMRs (B, C) and printouts (D) are secondary records.
Correct answer:A (The EDC record).
References:
ICH E6(R2), §1.51 (Definition of source data).

NEW QUESTION # 44
According to the CFR, which of the following is a complete and accurate list of the signatures required on the short form consent document?

- A. The subject or else the subject's legally authorized representative; the witness
- B. The subject or else the subject's legally authorized representative
- C. The subject or else the subject's legally authorized representative; the investigator or else the investigator's designee
- D. The subject or else the subject's legally authorized representative; the investigator or else the investigator's designee; the witness

Answer: A

Explanation:
Theshort form consent processis permitted when the subject is presented with a brief written statement that they were informed of the study, supplemented by an oral presentation.
* 21 CFR 50.27(b)(2):Requires the short form to be signed by the subject (or legally authorized representative)and a witness.
* The witness ensures that oral consent was properly conveyed and understood.
* The person obtaining consent must sign aseparate written summary, but not the short form itself.
Thus, the accurate answer isA: subject (or LAR) + witness.
References:
21 CFR 50.27(b)(2).

NEW QUESTION # 45
Protocol increases drug dose by 20%. Baseline: 370 mg/m². New dose = ?

- A. 492 mg/m²
- B. 444 mg/m²
- C. 420 mg/m²
- D. 400 mg/m²

Answer: B

Explanation:
370 × 1.20 =444 mg/m².
Accurate dosing calculations are critical for protocol adherence and patient safety.
References:Standard pharmacology dose adjustment principles; ICH E6(R2) §4.5.1.

NEW QUESTION # 46
For a Significant Risk device study, an investigator must report within 5 working days which event?

- A. Unanticipated adverse effect

- B. Completion of investigation
- C. Withdrawal of FDA approval
- D. Emergency deviation

Answer: D

Explanation:
* 21 CFR 812.150(a)(4):Any deviation from investigational plan made to protect the life or physical well- being of a subject in an emergency must be reported to the sponsor and IRBwithin 5 working days.
* Unanticipated adverse device effects have a 10-day reporting window.
References:21 CFR 812.150(a)(4).

NEW QUESTION # 47
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