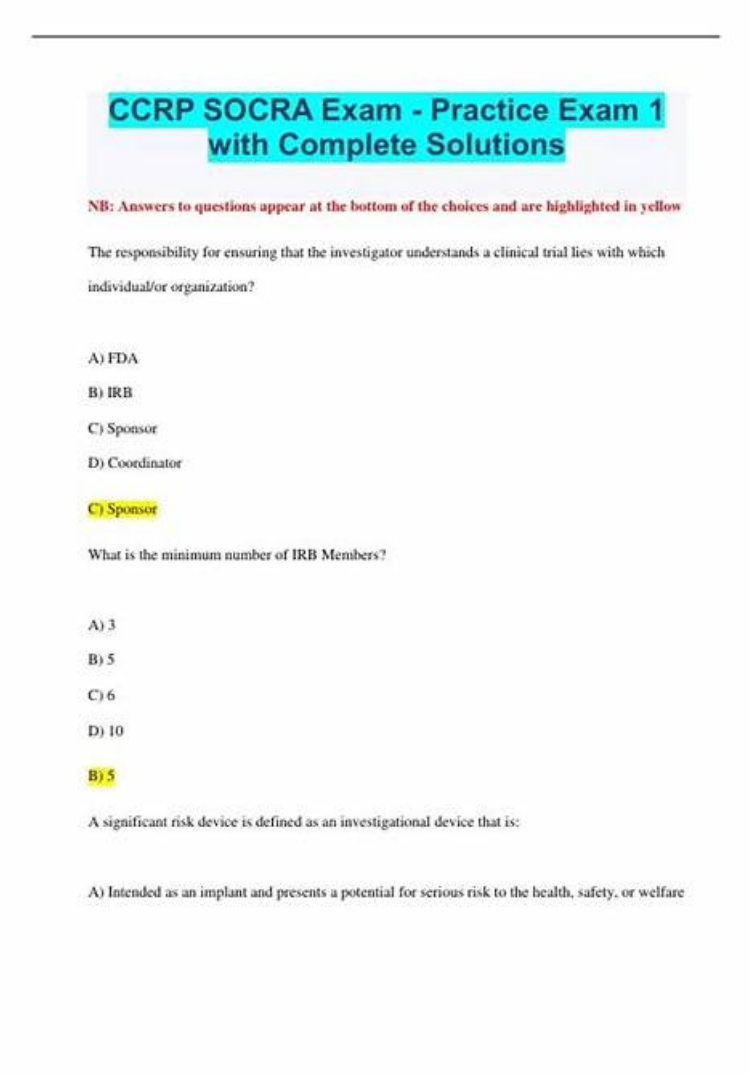
CCRP Exam Certification | CCRP Practice Engine



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

What's more, part of that ExamsReviews CCRP dumps now are free: https://drive.google.com/open?id=1Zil2lbCr_hN7ESLBYoro9tNUwgMFpNNp

It is possible for you to easily pass CCRP exam. Many users who have easily pass CCRP exam with our CCRP exam software of ExamsReviews. You will have a real try after you download our free demo of CCRP Exam software. We will be responsible for every customer who has purchased our product. We ensure that the CCRP exam software you are using is the latest version.

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 CCRP Practice Engine & Standard CCRP Answers

With CCRP fabulous dump, you have no fear of losing the exam. Actually, the state of the art content in dumps leaves no possibility of confusion for the candidate and the deficiency of information to answer questions in the real exam. Only a few days' effort can equip you thoroughly and thus impart you enormous confidence to appear in CCRP Exam and ace it in your very first go.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q102-Q107):

NEW QUESTION # 102
During the closeout visit, a monitor is completing the documentation of reconciliation of investigational product. All packaging, as well as the used and unused investigational product, are being returned to the sponsor for disposition. Which of the following documents wouldNOTbe required to be filed at the research site?

- A. A certificate of investigational product destruction
- B. Records of investigational product shipment
- C. Investigational product inventory forms
- D. Investigational product accountability forms

Answer: A

Explanation:
Investigators must document the receipt, use, return, or alternative disposition of investigational product (IP).
* ICH E6(R2) 4.6.3:Requires investigators to maintain records of IP delivery, inventory, use by subjects, and return/disposition.
* ICH E6(R2) 8.2.14-8.2.16:Essential documents include shipment records, accountability logs, and inventory records.
However,certificates of destructionare generated and retained by the sponsor (or authorized destruction facility), not required at the site unless the destruction occurred there. In this scenario, all IP was returned to the sponsor, so no destruction certificate would exist at the site.
Thus, the correct answer isD (Certificate of destruction).
References:
ICH E6(R2), §4.6.3 (Investigator product accountability).
ICH E6(R2), §8.2.14-8.2.16 (Essential documents).

NEW QUESTION # 103
In accordance with the CFR, which of the following statements regarding the informed consent document is correct?

- A. It is signed and dated by the subject's legally authorized representative
- B. It identifies all of the applicable mandated basic elements

- C. It is signed and dated by the IRB/IEC chair
- D. It does not identify some of the applicable mandated basic elements

Answer: B

Explanation:
The informed consent document (ICD) is a cornerstone of ethical clinical research, ensuring voluntary participation and protection of subject rights.
* 21 CFR 50.25(a):Requires the consent form to containall basic elements, including study purpose, risks, benefits, alternatives, confidentiality, compensation, and voluntariness.
* ICH E6(R2) 4.8.10:Expands on these requirements, ensuring the ICD contains every mandated element without omission.
Thus, the correct statement is that the ICDmust include all applicable mandated basic elements(D).
Options A and B confuse who signs-subjects or legally authorized representatives sign when applicable, not the IRB chair. Option C is incorrect because leaving out elements would violate compliance.
Correct answer:D.
References:
21 CFR 50.25(a).
ICH E6(R2), §4.8.10.

NEW QUESTION # 104
A subject on a multi-drug regimen could not tolerate a non-investigational drug. Can the investigational regimen continue?

- A. Only after sponsor and IRB approval
- B. Only for a short time, then change to placebo
- C. Yes, per protocol
- D. Only after medical monitor approval

Answer: A

Explanation:
* ICH E6(R2) 4.5.1:Investigators must follow the protocol approved by the IRB/IEC.
* Any modification that is not pre-specified must be approved by sponsor and IRB before continuing.
Only deviations eliminating immediate hazard can be done without prior approval; in this case, continuation requires sponsor + IRB agreement.
References:ICH E6(R2) §4.5.1.

NEW QUESTION # 105
In accordance with the ICH GCP Guideline, when a sponsor transfers trial-related duties andfunctions to a contract research organization (CRO), who is ultimately responsible for the quality and integrity of the trial data?

- A. The investigator
- B. The sponsor
- C. The CRO
- D. The IRB/IEC

Answer: B

Explanation:
Outsourcing does not shift ultimate responsibility away from the sponsor. Exact extract:
* ICH E6(R2) 5.2.1: "A sponsor may transfer any or all of the sponsor's trial-related duties... to a CRO, but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor."Hence, D is correct.
References:
ICH E6(R2) Good Clinical Practice, §5.2.1 (Sponsor/CRO).==========

NEW QUESTION # 106
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 psychological status of the children
- C. The physiological status of the children
- D. The economic status of the children

Answer: B

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 # 107
.....

If you are troubled with CCRP exam, you can consider down our free demo. You will find that our latest CCRP exam torrent are perfect paragon in this industry full of elucidating content for exam candidates of various degree to use. Our results of latest CCRP Exam Torrent are startlingly amazing, which is more than 98 percent of exam candidates achieved their goal successfully. That also proved that CCRP Test Dumps ensures the accuracy of all kinds of learning materials is extremely high.