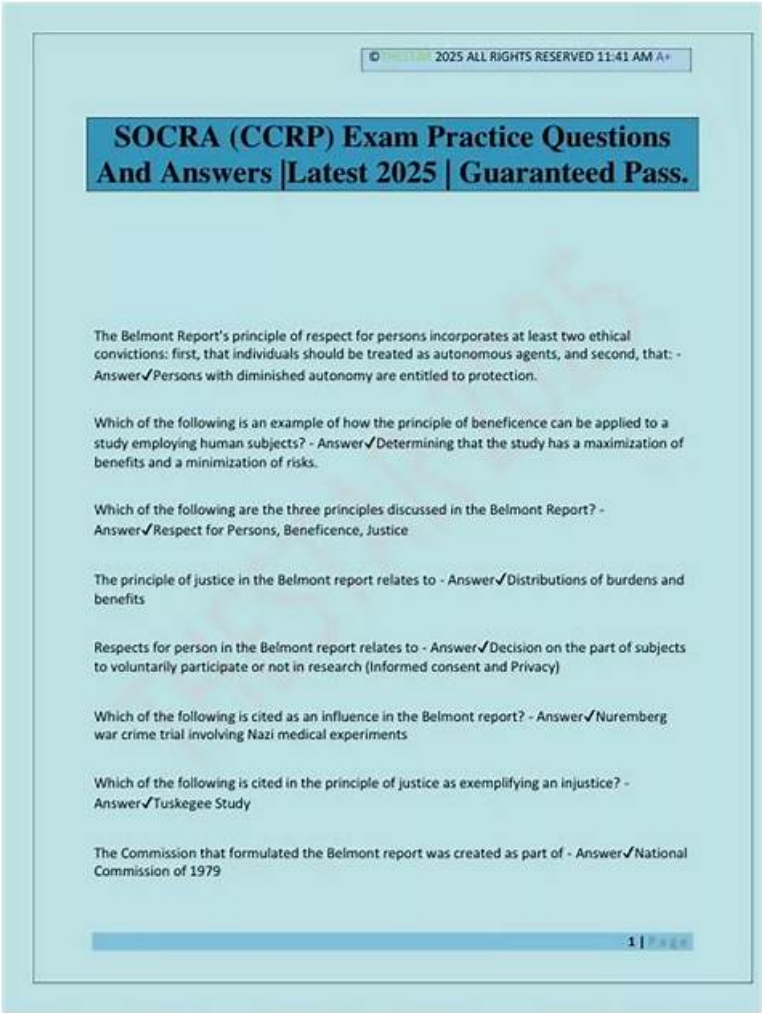
SOCRA CCRP Exam Questions–Secret To Pass On First Attempt



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Regular practice can give you the skills and confidence needed to perform well on your CCRP exam. By practicing your Certified Clinical Research Professional (CCRP) (CCRP) exam regularly, you can increase your chances of success and make sure that all of your hard work pays off when it comes time to take the test. We understand that every Certified Clinical Research Professional (CCRP) (CCRP) exam taker has different preferences. To make sure that our Certified Clinical Research Professional (CCRP) (CCRP) preparation material is accessible to everyone, we made it available in three different formats. You can choose the most suitable and convenient one for you.

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.

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q103-Q108):

NEW QUESTION # 103
Which of the following is one of the responsibilities of an investigator who is NOT a sponsor?

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

Answer: B

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 # 104
According to ICH GCP, an electronic data capture (EDC) system must:

- A. Limit remote access

- B. Allow access across multiple platforms
- C. Allow for data changes and store audit trails
- D. Limit file sharing

Answer: C

Explanation:
* ICH E6(R2) 5.5.3(g):Requires audit trails for any data changes, recording date, time, and person responsible.This ensures traceability and regulatory compliance.
Other restrictions (B-D) are not mandated under ICH.
References:ICH E6(R2), §5.5.3(g).

NEW QUESTION # 105
A company's CEO wants to commercially promote a device under an IDE study. This plan:

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

Answer: C

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 # 106
Which of the following entities, if any, must provide an approval before an investigator may enroll subjects in a quality-of-life research questionnaire study?

- A. The IRB/IEC
- B. The Department of Health and Human Services
- C. The FDA or another regulatory authority
- D. No approvals are necessary if no pharmaceutical drugs are involved

Answer: A

Explanation:
Even if a study does not involve drugs, devices, or biologics, it still involveshuman subjectsand therefore requiresethical review by an IRB/IEC.
* 45 CFR 46.109(a):"An IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy."
* ICH E6(R2) 3.1.2:"The IRB/IEC should safeguard the rights, safety, and well-being of all trial subjects." Quality-of-life (QOL) studies may involve surveys, interviews, or questionnaires, but since they involve human participants, they are subject to human research protection regulations. FDA involvement is not required unless drugs or devices are tested. Similarly, HHS approval is not required unless the study is federally funded.
Thus, the correct answer isC (The IRB/IEC).
References:
45 CFR 46.109(a) (IRB review of research).
ICH E6(R2), §3.1.2 (IRB/IEC role in subject protection).

NEW QUESTION # 107
In accordance with the CFR, the sponsor (who is not a sponsor-investigator) is responsible for which of the following?

- A. Ensuring that the FDA and all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug

- B. Submitting progress reports to the reviewing IRB/IEC
- C. Overseeing the administration of the investigational drug to the subjects
- D. Maintaining case histories that record all observations and other data pertinent to the investigation

Answer: A

Explanation:
Sponsors are responsible for distributing safety updates across all investigators and the FDA.
* 21 CFR 312.55(b):"The sponsor shall promptly notify all participating investigators, and the FDA, of new significant adverse effects or risks with respect to the drug." Other responsibilities fall elsewhere:
* Case histories (C) are maintained by investigators (21 CFR 312.62(b)).
* Progress reports to IRBs (D) are the investigator's duty (21 CFR 312.66).
* Administration of investigational drug (A) is managed by the investigator at site level.
Thus, the correct answer isB (Ensuring FDA and investigators are promptly informed).
References:
21 CFR 312.55(b) (Sponsor notification requirements).

NEW QUESTION # 108
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