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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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CCRP Test Dumps Pdf & New CCRP Learning Materials

The Certified Clinical Research Professional (CCRP) is ideal whether you're just beginning your career in open source or planning to

advance your career. Moreover, the Certified Clinical Research Professional (CCRP) also serves as a great stepping stone to earning advanced Certified Clinical Research Professional (CCRP). Success in the CCRP exam is the basic requirement to get the a good job. You get multiple career benefits after cracking the Certified Clinical Research Professional (CCRP). These benefits include skills approval, high-paying jobs, and promotions. Read on to find more important details about the SOCRA CCRP Exam Questions.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q122-Q127):

NEW QUESTION # 122
An investigator received an updated informed consent form (ICF) from the sponsor for a study closed to enrollment. Subjects are only in long-term follow-up. The change related to frequent radiation imaging at screening, with no change to drug safety profile. Who must the investigator notify first?

- A. Sub-investigators
- B. No notification is required
- C. Participants in long-term follow-up
- D. The IRB/IEC

Answer: D

Explanation:
* 21 CFR 56.109(a):IRBs must review all changes to informed consent before implementation.
* ICH E6(R2) 4.8.2:If new information could affect willingness to continue, consent forms must be revised and approved by the IRB.
Even though screening is closed, the IRB/IEC must review the updated form before any subject re-consenting.
References:21 CFR 56.109(a); ICH E6(R2) §4.8.2.

NEW QUESTION # 123
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 CRO
- B. The investigator
- C. The sponsor
- D. The IRB/IEC

Answer: C

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 # 124
According to the CFR, when children who are wards of the state are enrolled into a clinical trial, what is required?

- A. Assenting children must self-represent
- B. Each child must have a patient advocate
- C. The investigator must represent the children
- D. The IRB/IEC must include a member who advocates for the children

Answer: D

Explanation:
Children who are wards of the state receiveadditional protectionsin clinical research.
* 45 CFR 46.409(b):For research involving wards, "the IRB shall require appointment of an advocate for each child, in addition to

any guardian or other advocate who would ordinarily be provided."
* The advocate must have background and experience to act in the child's best interest and cannot be associated with the research.
Thus, anIRB-appointed advocateis mandatory to ensure independent representation of the ward's rights.
References:45 CFR 46.409(b).

NEW QUESTION # 125
During an audit for a Phase II IND study, the auditor identified unreported serious protocol deviations. Which party must take prompt action to ensure compliance?

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

Answer: D

Explanation:
The sponsor holds ultimate responsibility for trial oversight and compliance.
* ICH E6(R2) 5.20.1:If noncompliance is discovered, the sponsor must "take prompt action to secure compliance" and, if necessary, terminate participation of the investigator/institution.
* 21 CFR 312.56(b):Sponsors must ensure proper conduct and report investigators who fail to comply to the FDA and IRB.
While investigators commit to protocol adherence, once deviations are identified,the sponsor must actto safeguard subjects and trial validity.
References:ICH E6(R2) §5.20.1; 21 CFR 312.56(b).

NEW QUESTION # 126
Upon completion of a study, the investigator should do which of the following?

- A. Ensure that all payments from sponsor have been received
- B. Provide the IRB/IEC a final report, but only if the study has a positive outcome
- C. Compile site data, publish the study results, and submit the publication to the IRB/IEC as the final report
- D. As soon as possible, provide the IRB/IEC with a final report that summarizes the trial's outcome

Answer: D

Explanation:
Investigators must formally close out a trial with the IRB/IEC.
* ICH E6(R2) 4.13.2:"Upon completion of the trial, the investigator/institution should provide the IRB
/IEC with a summary of the trial's outcome."
* 21 CFR 312.66:Reinforces investigator's duty to keep IRB informed throughout study lifecycle.
This applies regardless of whether outcomes were positive, negative, or inconclusive. IRBs are not concerned with sponsor payments (B) or publications (D).
Thus, the correct answer isA (Provide final report to IRB/IEC).
References:
ICH E6(R2), §4.13.2 (Final reporting requirement).

NEW QUESTION # 127
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