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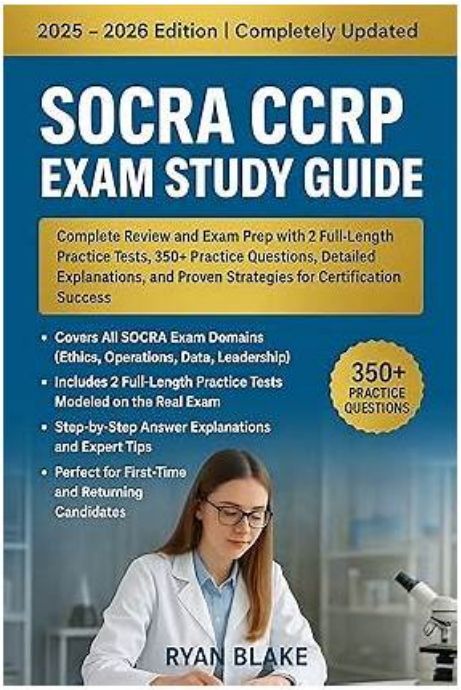

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SOCRA CCRP Exam Syllabus Topics:

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.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q72-Q77):

NEW QUESTION # 72
In order to meet recruitment goals, a sponsor is adding a new site to a multi-center study. Which of the following documents should the sponsor obtain from a new site prior to starting research at the site?

- A. The site's accreditation certificate
- B. The site's SOPs
- C. The delegation of duties log
- D. The IRB/IEC trial approval documentation

Answer: D

Explanation:
* ICH E6(R2) 4.4.1:"Before initiating a trial, the investigator/institution should have written and dated approval/favorable opinion from the IRB/IEC."
* Sponsors must confirm IRB approval before authorizing initiation.
References:ICH E6(R2), §4.4.1.

NEW QUESTION # 73
An investigator's responsibilities for conducting clinical trials include:

- A. Maintaining IRB meeting minutes
- B. Administering or overseeing investigational drug administration
- C. Observing preclinical drug effects
- D. Maintaining financial documentation for study staff

Answer: B

Explanation:
* ICH E6(R2) 4.6.1:The investigator is responsible for investigational product accountability at the site.
* 21 CFR 312.61:Investigators must administer the investigational drug only to subjects under their supervision.
The IRB maintains meeting minutes (A), preclinical studies are sponsor tasks (B), and financial interest documentation (C) is covered under sponsor reporting. Thus,D is correct.
References:ICH E6(R2) §4.6.1; 21 CFR 312.61.

NEW QUESTION # 74
If a subject experiences a serious adverse event related to the study drug and only minimal information is available, the investigator must submit the information to the:

- A. Sponsor and IRB/IEC immediately, then update later
- B. Sponsor and IRB/IEC within seven days
- C. Sponsor and IRB/IEC within five days
- D. IRB/IEC immediately, then sponsor when full details are available

Answer: A

Explanation:
* ICH E6(R2) 4.11.1:Investigators must "immediately report all serious adverse events to the sponsor except for those the protocol identifies as not requiring immediate reporting."
* IRB must also be informed promptly per21 CFR 312.64(b).
* Follow-up information is submitted later as available.
References:ICH E6(R2), §4.11.1; 21 CFR 312.64(b).

NEW QUESTION # 75
Protecting prisoners' rights to voluntarily participate in research is an example of which Belmont principle?

- A. Dignity
- B. Beneficence
- C. Justice
- D. Respect for Persons

Answer: D

Explanation:
* Belmont Report:"Respect for Persons" incorporates two ethical convictions: treating individuals as autonomous agents and protecting those with diminished autonomy (e.g., prisoners).
* Prisoners require special safeguards because of restricted liberty and potential coercion.
References:Belmont Report (1979).

NEW QUESTION # 76
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 investigator or else the investigator's designee
- B. The subject or else the subject's legally authorized representative; the investigator or else the investigator's designee; the witness
- C. The subject or else the subject's legally authorized representative; the witness
- D. The subject or else the subject's legally authorized representative

Answer: C

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 # 77
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