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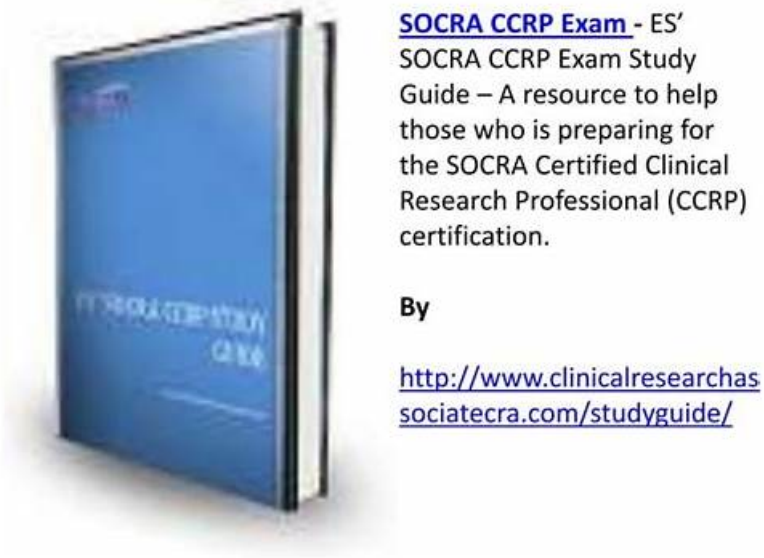

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SOCRA CCRP Exam Syllabus Topics:

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.

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q27-Q32):

NEW QUESTION # 27
A clinical investigator wants to publish a subject's unique results. The consent form did not mention publication. What is required?

- A. Consent from subject
- B. Nothing further
- C. Approval from monitor
- D. IRB chair approval

Answer: A

Explanation:
* ICH E6(R2) 4.8.10(n):Consent must include explanation about confidentiality and possible publication.
* If not included, specificsubject consentmust be obtained before publishing identifiable results.
Thus, subject's explicit permission is required.
References:ICH E6(R2) §4.8.10(n).

NEW QUESTION # 28
Which of the following should a clinical investigator include in a submission to an IRB/IEC for a Phase IV drug study?

- A. The drug development and marketing plan
- B. The investigator's clinical trial agreement with the sponsor
- C. The itemized study budget
- D. The amount of payments and compensation to subjects

Answer: D

Explanation:
For IRB/IEC submissions, investigators must disclose subject-related information that may impact voluntariness or fairness of participation.
* 21 CFR 56.111(a)(3):The IRB must ensure that subject selection is equitable.
* 21 CFR 50.25(a)(3):Requires disclosure of "any compensation and/or medical treatments available if injury occurs."
* ICH E6(R2) 4.8.10(n):Informed consent should describe "any compensation and/or reimbursement to subjects."
Thus,compensation amountsmust be reviewed by IRB/IEC to ensure they are not coercive or excessive.
Budgets (A), marketing plans (C), and contracts (D) are administrative and not part of IRB submission requirements.
Correct answer:B (The amount of payments and compensation to subjects).
References:
21 CFR 50.25(a)(3).
ICH E6(R2), §4.8.10(n).

NEW QUESTION # 29
An investigator's responsibilities for conducting clinical trials include:

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

Answer: A

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 # 30
The study coordinator for a new Phase III vaccine study is preparing documents for IRB/IEC submission.
According to the ICH GCP Guidelines, which of the following documents should be included in the submission?

- A. Case report forms
- B. Recruitment materials
- C. The investigators' CVs
- D. Local lab normal ranges

Answer: B

Explanation:
IRBs/IECs are responsible for ensuring that subject recruitment is ethical and not coercive.
* ICH E6(R2) 3.1.2:The IRB/IEC safeguards subjects by reviewing recruitment procedures and materials.
* 21 CFR 56.111(a)(3):Requires equitable subject selection, which extends to advertisements and recruitment.
* FDA Guidance on Recruiting Study Subjects (1998):States that "advertisements and recruitment materials must be reviewed and approved by the IRB prior to use." While CVs (D) and lab ranges (A) are essential documents for study feasibility and quality, they are not mandatory for IRB approval package. CRFs (B) are sponsor tools for data collection, not subject-facing, and thus not reviewed by IRBs.
Correct answer:C (Recruitment materials).
References:
ICH E6(R2), §3.1.2.
FDA Recruitment Guidance, 1998.

NEW QUESTION # 31
According to ICH GCP, an electronic data capture (EDC) system must:

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

Answer: D

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 # 32
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