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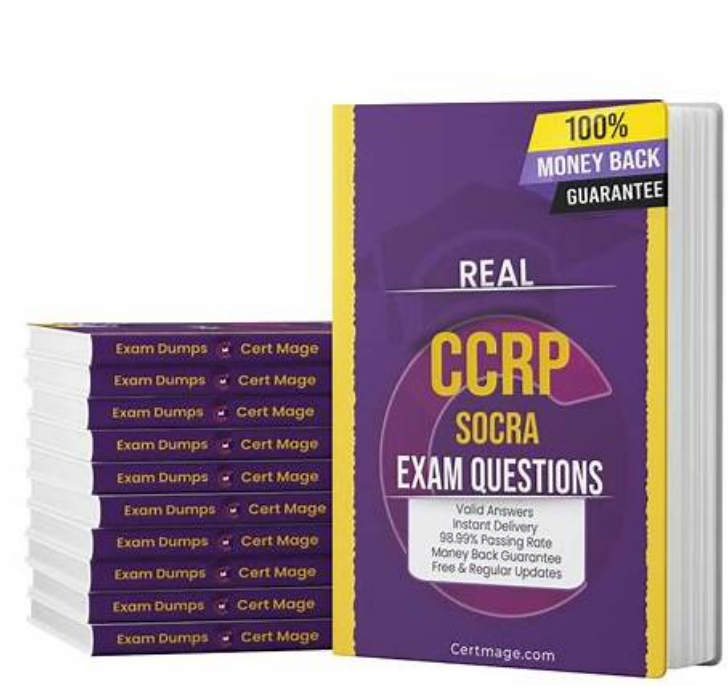

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SOCRA CCRP Exam Syllabus Topics:

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 (Q129-Q134):

NEW QUESTION # 129
Which case history documents must be at both sponsor and site?

- A. Signed informed consent forms
- B. Study visit notes
- C. Case report forms (CRFs)
- D. Medical records

Answer: C

Explanation:
* ICH E6(R2) 1.11:CRFs are documents used to record protocol-required data reported to sponsor.
* Sites keep originals; sponsor retains copies.Consent forms and medical records stay at site only.
References:ICH E6(R2), §1.11.

NEW QUESTION # 130
Which of the following is an example of an additional protection required when conducting research on children?

- A. The investigator must obtain age-appropriate assent as determined by the IRB/IEC
- B. Parents must be present during all procedures
- C. The study must be approved by a central pediatric IRB
- D. There must be an impartial advocate present during the consent process

Answer: A

Explanation:
Children are a vulnerable population. U.S. regulations require IRB/IEC judgment about when and howassent is obtained, in addition

to parental permission. Exact extracts:
* 45 CFR 46.408(a): "The IRB shall determine...whether and to what extent children are capable of providing assent."
* ICH E6(R2) 4.8.12: "Where a subject is unable to give consent personally,assent should be obtained when appropriate, in accordance with applicable regulatory requirement(s)."Thus, the additional protection is IRB-determined, age-appropriate assent (B). Options A, C, and D are not universal requirements for all pediatric research.
References:
ICH E6(R2) Good Clinical Practice, §4.8.12 (Informed consent/assent).
45 CFR 46 Subpart D-Additional Protections for Children, §46.408(a).==========

NEW QUESTION # 131
Which of the following elements should NOT influence the investigator's ability to obtain endpoint data?

- A. Participant compliance
- B. Complexity of study
- C. Length of study follow-up
- D. Complexity of CRFs

Answer: D

Explanation:
* Endpoint data collection is based onprotocol designand subject compliance, not CRF formatting.
* ICH E6(R2) 4.9.0:Investigator responsible for data accuracy regardless of CRF complexity.
References:ICH E6(R2), §4.9.0.

NEW QUESTION # 132
A monitor is conducting a site closeout visit. The study site kept electronic medical records and source documents in a system verified to be 21 CFR Part 11 compliant. The monitor reviewed all electronic documents by logging into the system with a unique login ID and password. In addition to the essential document file, which of the following sets of documents should be provided to the monitor during the study closeout visit?

- A. Printouts of electronic source documents and the remaining investigational product
- B. Informed consent documents and investigational product documentation
- C. A copy of the final report for the IRB and investigational product shipment records
- D. Informed consent documents and printouts of electronic source documents

Answer: B

Explanation:
During study closeout, the monitor verifies subject protection, protocol compliance, and investigational product accountability.
* ICH E6(R2) 8.1 & 8.4:Lists essential documents to be verified at closeout, including signed informed consent forms and investigational product accountability records.
* 21 CFR Part 11:Ensures electronic records are valid, so printed copies are not always necessary unless required for auditing.
Thus, the critical items for monitor review at closeout areinformed consent forms(to confirm subject protection) andinvestigational product documentation(to confirm reconciliation and disposition).
Correct answer:D.
References:
ICH E6(R2), §8.1, §8.4.

NEW QUESTION # 133
A research assistant on a study was recently promoted to a clinical research coordinator (CRC) role after one year on the study. In order to fulfill the significant new responsibilities, the CRC completed additional institutional training. According to ICH GCP Guidelines and 21 CFR, which of the following must be filed in the regulatory binder?

- A. The letter documenting the promotion to a CRC
- B. An updated curriculum vitae
- C. An updated performance review summary
- D. A brochure from the training course

Answer: B

Explanation:
The regulatory binder (investigator site file) must contain documents verifying qualifications of all personnel.
These include curricula vitae (CVs), professional licenses, and training certificates.
ICH E6(R2) 4.1.5: "The investigator should ensure that all persons assisting with the trial are qualified by education, training, and experience... Current curriculum vitae and/or other relevant documents evidencing qualifications should be maintained."
21 CFR 312.53(c)(1): Sponsors must select investigators qualified "by training and experience," and investigators must provide sufficient documentation, typically updated CVs.
Letters of promotion (A), training brochures (B), or performance reviews (C) may remain in personnel files but are not required regulatory documents. The only acceptable regulatory proof is an updated CV (D), which reflects the individual's training and qualifications for their new role.
Therefore, the correct answer is D (Updated CV). This ensures compliance with ICH and FDA requirements for staff qualification documentation in clinical research.
References:
ICH E6(R2) Good Clinical Practice, §4.1.5 (Investigator responsibilities for staff qualification).
21 CFR 312.53(c)(1) (Investigator qualifications and documentation).

NEW QUESTION # 134
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