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SOCRA CCRP Exam Syllabus Topics:

Topic	Details
Topic 1	• 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.
Topic 2	• 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.

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q92-Q97):

NEW QUESTION # 92
A physician with 20 years of experience is planning to be the site investigator for a multi-center, Phase I oncology clinical trial. In accordance with the ICH GCP Guideline, which of the following documents should the physician provide to the sponsor and the IRB/IEC?

- A. Proof of citizenship
- B. A copy of medical license
- C. A curriculum vitae
- D. A letter of recommendation from a fellow physician

Answer: C

Explanation:
Investigators must provideevidence of qualificationsto conduct the study.
* ICH E6(R2) 4.1.1:"The investigator should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial."
* ICH E6(R2) 8.2.10:Essential documents include thecurriculum vitae (CV)or other documents evidencing investigator qualifications, submitted to both sponsor and IRB/IEC.
Proof of citizenship (A) and letters of recommendation (B) are irrelevant. A copy of a medical license (D) may be provided but isnot specifically requiredby ICH. The CV is the universally required document.
Thus, the correct answer isC (Curriculum vitae).
References:
ICH E6(R2), §4.1.1 (Investigator qualifications).
ICH E6(R2), §8.2.10 (Essential documents: CV).

NEW QUESTION # 93
Which of the following is an example of an additional protection required when conducting research on children?

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

Answer: B

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 # 94
During an IND study closeout, a monitor discovered remaining investigational product. Which procedures must be followed for disposition?

- A. Sponsor's procedures
- B. Regulatory authority's procedures
- C. Dispensing pharmacy's procedures
- D. IRB/IEC's procedures

Answer: A

Explanation:
* ICH E6(R2) 5.13.3:The sponsor is responsible for the supply, storage, and final disposition of investigational product.

* 21 CFR 312.59:Sponsors must assure return or proper disposition of unused supplies.
* Sites must followsponsor's written proceduresfor reconciliation, return, or destruction, not IRB or pharmacy processes.
References:ICH E6(R2) §5.13.3; 21 CFR 312.59.

NEW QUESTION # 95
According to the ICH/GCP Guideline, which of the following should a sponsor provide to the clinical investigator before entering into a clinical trial agreement?

- A. Adequate resources
- B. Staff training
- C. Proper equipment
- D. The protocol

Answer: D

Explanation:
Before an investigator can commit to conducting a trial, they must review thestudy protocol.
* ICH E6(R2) 4.5.1:The investigator should conduct the trial in compliance with theprotocol approved by the IRB/IEC and sponsor.
* ICH E6(R2) 4.2.3:The investigator should be thoroughly familiar with the appropriate use of the investigational product as described in the investigator's brochure and the current approved protocol.
Although resources, training, and equipment are important, the fundamental step is provision of theprotocol, which forms the legal and ethical framework for study conduct. No trial agreement can be finalized until both parties agree on theprotocol details.
References:ICH E6(R2), §§4.2.3, 4.5.1.

NEW QUESTION # 96
Sponsor must maintain drug disposition records for how long after marketing approval?

- A. 5 years
- B. 2 years
- C. 3 years
- D. 1 year

Answer: B

Explanation:
* 21 CFR 312.57(c):"Sponsors shall retain records for2 years after a marketing application is approvedor if not approved, 2 years after shipment and delivery of investigational drug for investigation." References:21 CFR 312.57(c).

NEW QUESTION # 97
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