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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.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q12-Q17):

NEW QUESTION # 12
A pharmaceutical company is developing a biologic study. In accordance with ICH, which of the following items should be included in an investigator's brochure (IB)?

- A. Results of recent nude mouse study
- B. Dispensing instructions
- C. Schedule of events
- D. Lab draw requirements

Answer: A

Explanation:
TheInvestigator's Brochure (IB)compilesclinical and nonclinical dataon an investigational product relevant to human study.
* ICH E6(R2) 7.2.3:The IB should summarizenonclinical pharmacology, toxicology, pharmacokinetics, and efficacy data, including results of animal studies.
* ICH E6(R2) 7.2.4:It should also includeavailable clinical trial dataand safety experience.
The "results of recent nude mouse study" (B) are nonclinical data, which appropriately belong in the IB. Lab draw requirements (A), dispensing instructions (C), and schedules of events (D) are operational/procedural and are found in theprotocol, not the IB.
Thus, the correct answer isB (Results of recent nude mouse study).
References:
ICH E6(R2), §7.2.3-7.2.4 (Contents of Investigator's Brochure).

NEW QUESTION # 13
The sponsor withdrew an IND due to safety. Who must be notified promptly, in addition to FDA?

- A. Site coordinator
- B. Investigational pharmacies
- C. OHRP
- D. Reviewing IRBs/IECs

Answer: D

Explanation:
* 21 CFR 312.56(d):If an IND is withdrawn for safety, the sponsor must notifyFDA and all participating investigators, who in turn notify IRBs.
* Ensures subjects are protected and sites stop enrollment.
References:21 CFR 312.56(d).

NEW QUESTION # 14
A research protocol requires patients to complete a patient reported outcome questionnaire in the sponsor's electronic data capture (EDC) system. What is the source data?

- A. A printout of the EDC record
- B. The electronic medical record
- C. The EDC record
- D. A printout of the electronic medical record

Answer: C

Explanation:
Source data areoriginal records where data are first recorded.
* ICH E6(R2) 1.51:Defines source data as "all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial." Since subjects directly enter responses into the EDC, theEDC record itself is the original source document.
EMRs (B, C) and printouts (D) are secondary records.
Correct answer:A (The EDC record).
References:
ICH E6(R2), §1.51 (Definition of source data).

NEW QUESTION # 15
In accordance with the CFR, which of the following statements regarding the informed consent document is correct?

- A. It does not identify some of the applicable mandated basic elements
- B. It is signed and dated by the subject's legally authorized representative
- C. It is signed and dated by the IRB/IEC chair
- D. It identifies all of the applicable mandated basic elements

Answer: D

Explanation:
The informed consent document (ICD) is a cornerstone of ethical clinical research, ensuring voluntary participation and protection of subject rights.
* 21 CFR 50.25(a):Requires the consent form to containall basic elements, including study purpose, risks, benefits, alternatives, confidentiality, compensation, and voluntariness.
* ICH E6(R2) 4.8.10:Expands on these requirements, ensuring the ICD contains every mandated element without omission.
Thus, the correct statement is that the ICDmust include all applicable mandated basic elements(D).
Options A and B confuse who signs-subjects or legally authorized representatives sign when applicable, not the IRB chair. Option C is incorrect because leaving out elements would violate compliance.
Correct answer:D.
References:
21 CFR 50.25(a).
ICH E6(R2), §4.8.10.

NEW QUESTION # 16
Which document was created as a response to unethical WWII human experiments?

- A. Nuremberg Code
- B. Declaration of Helsinki
- C. Food, Drug, and Cosmetic Act

- D. Belmont Report

Answer: A

Explanation:
* TheNuremberg Code (1947)established voluntary consent as essential following Nazi war crimes.
* Helsinki (1964) built upon it; Belmont Report (1979) refined U.S. ethics.
Thus, the correct foundational WWII document isthe Nuremberg Code.
References:Nuremberg Code, 1947.

NEW QUESTION # 17
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