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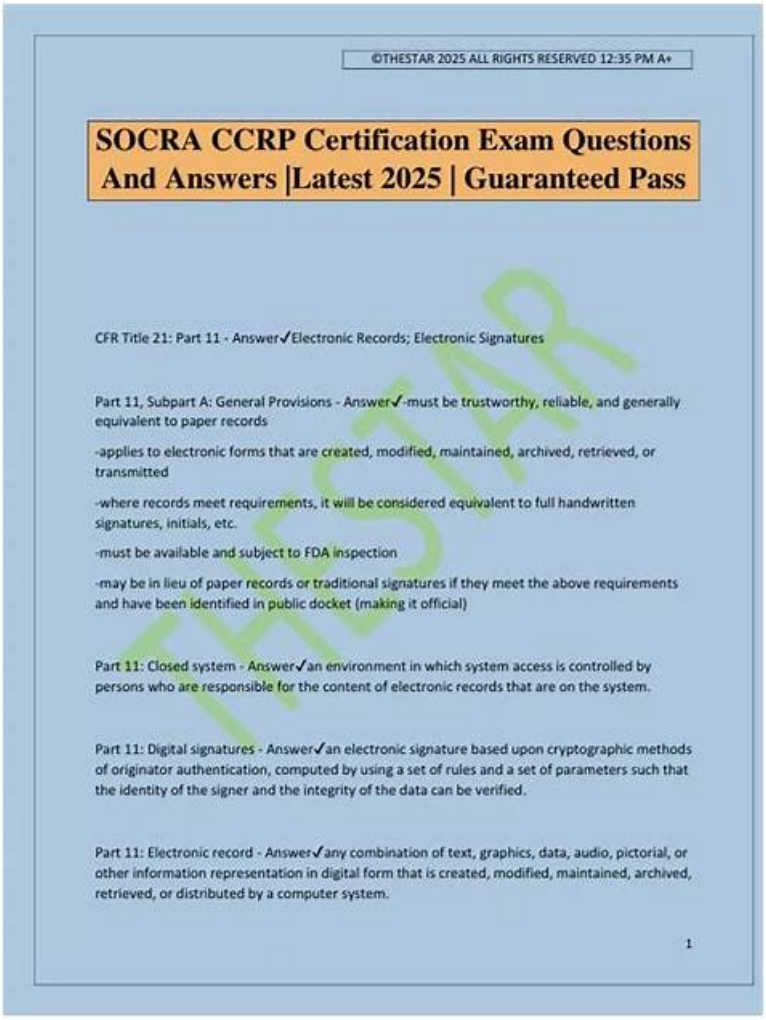

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SOCRA CCRP Exam Syllabus Topics:

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.

CCRP Minimum Pass Score | Practice CCRP Test

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q60-Q65):

NEW QUESTION # 60
A sponsor received a report from an investigator regarding the investigator's use of an investigational device without having obtained informed consent. The sponsor must submit a copy of the report to the FDA within:

- A. 10 working days
- B. 5 working days
- C. 30 working days
- D. 1 day

Answer: B

Explanation:
Informed consent is a fundamental ethical requirement. If it is violated in a device trial, the FDA requires rapid reporting.
* 21 CFR 812.150(b)(5):States that a sponsor shall submit to FDA "any report of use of a device without obtaining informed consent, within5 working daysafter the sponsor first receives notice of such use."
* This expedited reporting ensures FDA oversight of serious violations and protection of human subjects.
Incorrect options:
* A (1 day) is overly strict and not codified.
* C (10 days) and D (30 days) are too delayed to meet regulatory intent of immediate oversight.
Thus, the correct timeline iswithin 5 working days.
References:
21 CFR 812.150(b)(5).

NEW QUESTION # 61
According to ICH GCP, sponsor-specific essential documents must be retained until:

- A. 3 years after last approval
- B. 2 years after last approval and no pending applications

- C. 25 years after last approval
- D. 5 years after last approval

Answer: B

Explanation:
* ICH E6(R2) 5.5.12 & 8.1:Essential documents must be retained2 years after the last approval of a marketing application in an ICH region and until no applications are pending, or2 years after discontinuation of development.
This ensures availability for inspection.
References:ICH E6(R2) §§5.5.12, 8.1.

NEW QUESTION # 62
Which document was created as a response to unethical WWII human experiments?

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

Answer: B

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 # 63
In accordance with the ICH GCP Guideline, who is responsible for the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the case report forms and in all required reports?

- A. The contract research organization monitor
- B. The quality control specialist
- C. The clinical investigator
- D. The IRB/IEC coordinator

Answer: C

Explanation:
The investigator holds ultimate responsibility for all data reported.
* ICH E6(R2) 4.9.1:"The investigator is responsible for the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor on the CRFs and all required reports."
* Monitors (D) verify data accuracy but are not responsible for data quality. Quality specialists (B) and IRB staff (C) have no role in data entry.
Correct answer:A (The clinical investigator).
References:
ICH E6(R2), §4.9.1.

NEW QUESTION # 64
According to the CFR and the ICH GCP Guideline, which of the following must be submitted to the IRB after completion of the trial at the site?

- A. The final report
- B. The final subject enrollment log
- C. The data safety monitoring summary
- D. The monitoring close-out visit report

Answer: A

Explanation:
When a trial ends at a site, the investigator has an obligation to submit a final report to the IRB/IEC. This is outlined in both ICH and CFR:
ICH E6(R2) 4.13: "Upon completion of the trial, the investigator should provide the IRB/IEC with a summary of the trial's outcome."
21 CFR 312.66: Requires investigators to "report to the IRB all changes in the research activity and all unanticipated problems involving risk, and to provide reports at the end of the study." The final report provides closure and documentation that the study was conducted ethically and in compliance with regulatory standards. Other documents listed in the options (monitoring reports, DSMB summaries, subject logs) may be retained by the sponsor or site, but they are not mandated for IRB submission.
Thus, the correct answer is A (Final Report). This ensures the IRB/IEC has an accurate record of study completion, outcome, and compliance with ethical oversight.
References:
ICH E6(R2), §4.13 (Final reporting to IRB/IEC).
21 CFR 312.66 (IRB review and reporting).

NEW QUESTION # 65
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