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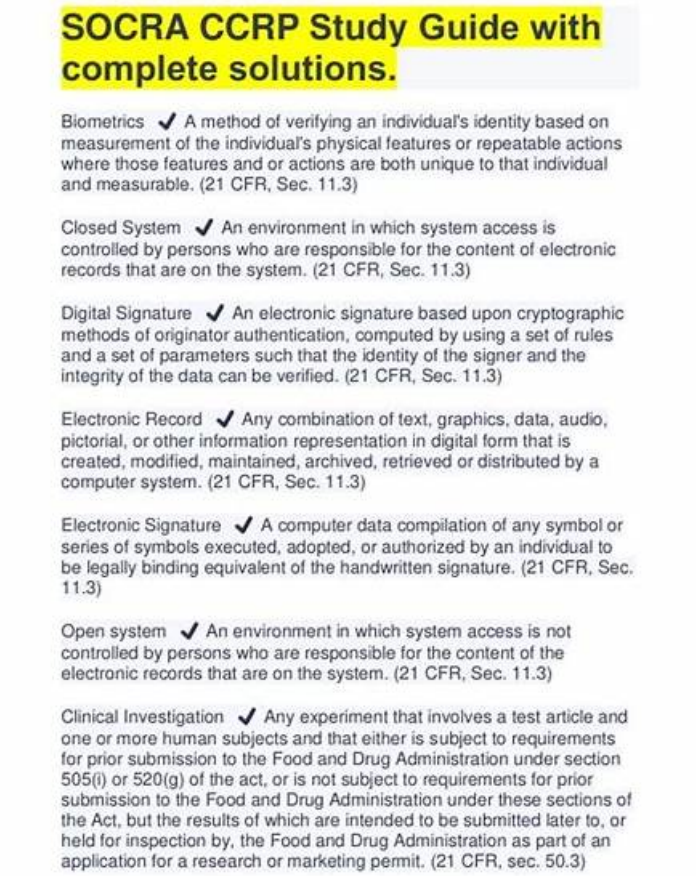

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Biometrics ✓ A method of verifying an individual's identity based on measurement of the individual's physical features or repeatable actions where those features and or actions are both unique to that individual and measurable. (21 CFR, Sec. 11.3)

Closed System ✓ An environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system. (21 CFR, Sec. 11.3)

Digital Signature ✓ An electronic signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified. (21 CFR, Sec. 11.3)

Electronic Record ✓ Any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved or distributed by a computer system. (21 CFR, Sec. 11.3)

Electronic Signature ✓ A computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be legally binding equivalent of the handwritten signature. (21 CFR, Sec. 11.3)

Open system ✓ An environment in which system access is not controlled by persons who are responsible for the content of the electronic records that are on the system. (21 CFR, Sec. 11.3)

Clinical Investigation ✓ Any experiment that involves a test article and one or more human subjects and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the Act, but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. (21 CFR, sec. 50.3)

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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.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q66-Q71):

NEW QUESTION # 66
A study will enroll 420 subjects over 3.5 years. What is expected average monthly accrual?

- A. 0
- B. 1
- C. 2
- D. 3

Answer: C

Explanation:
420 subjects ÷ 42 months (3.5 years) =10 subjects/month.
However, "expected average" often rounds up to next whole number, ensuring enrollment goals are met. Thus,
11/monthis correct.
This calculation is important for feasibility assessments and protocol planning.
References:Standard feasibility calculations (ICH E6(R2) §5.6).

NEW QUESTION # 67
During an IND study closeout, a monitor discovered remaining investigational product. Which procedures must be followed for disposition?

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

Answer: B

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 # 68
An investigator discovered a new serious unanticipated adverse device effect. Who must they notify?

- A. Sponsor
- B. OHRP
- C. FDA
- D. Research pharmacist

Answer: A

Explanation:
* 21 CFR 812.150(a)(1):Investigators must report unanticipated adverse device effects to thesponsor within 10 working days.
* Sponsor is then responsible for notifying FDA and all investigators.
References:21 CFR 812.150(a)(1).

NEW QUESTION # 69
Protocol increases drug dose by 20%. Baseline: 370 mg/m². New dose = ?

- A. 444 mg/m²
- B. 400 mg/m²
- C. 492 mg/m²
- D. 420 mg/m²

Answer: A

Explanation:
370 × 1.20 =444 mg/m².
Accurate dosing calculations are critical for protocol adherence and patient safety.
References:Standard pharmacology dose adjustment principles; ICH E6(R2) §4.5.1.

NEW QUESTION # 70
The reviewing IRB/IEC determined that a minimal risk sponsor-investigator study is exempt from IRB/IEC review. How often, if ever, is the sponsor-investigator required to submit a continuing review to the IRB/IEC?

- A. There is no such requirement
- B. Every two years
- C. Exactly one time, at study closure
- D. Every year

Answer: A

Explanation:
Minimal risk studiesmay qualify for exemption or expedited review under45 CFR 46.101(b).
* 45 CFR 46.109(f):"Unless an IRB determines otherwise, continuing review of research is not required for research eligible for expedited review and determined to involve no more than minimal risk."
* ICH E6(R2) 3.1.4:Requires IRB review for clinical trials, but exemptions exist for minimal risk studies.
Therefore, once exempted, there isno requirement for continuing review, unless specifically required by the IRB. Submission at closure is optional depending on institutional policy but not a federal requirement.
Thus, the correct answer isD (No such requirement).
References:

45 CFR 46.109(f) (Exempt and expedited reviews).

NEW QUESTION # 71

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