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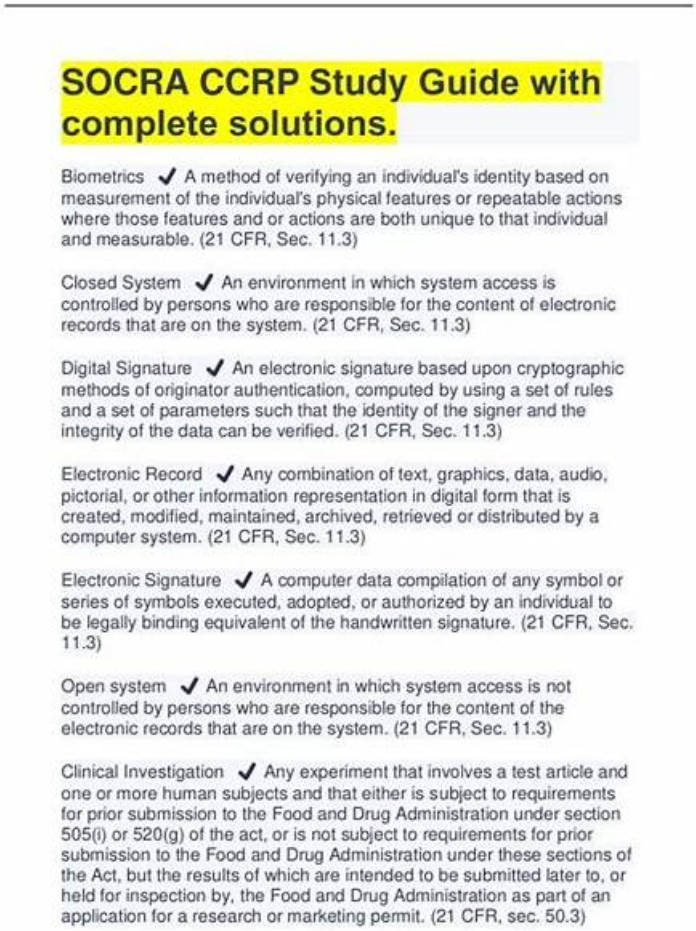

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Biometrics ✓ A method of verifying an individual's identity based on measurement of the individual's physical features or repeatable actions where those features and or actions are both unique to that individual and measurable. (21 CFR, Sec. 11.3)

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.

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q49-Q54):

NEW QUESTION # 49
A study team is preparing to initiate a Phase II trial for a novel colon cancer therapy. By signing the Form FDA 1572, the investigator is certifying that the investigator has:

- A. Confirmed that the site's SOPs are in place
- B. Obtained malpractice insurance
- C. Completed other relevant research projects
- D. Read and understood the investigator's brochure

Answer: D

Explanation:
Form FDA 1572 is the "Statement of Investigator" for IND studies.
* 21 CFR 312.53(c)(1)(vi)(b):Requires investigators to "read and understand the Investigator's Brochure."
* By signing, the investigator also agrees to comply with regulations, maintain records, and supervise study conduct.
Other options (B-D) are not part of 1572 requirements.
Correct answer:A.
References:
21 CFR 312.53(c)(1)(vi)(b).

NEW QUESTION # 50
An investigator received an updated informed consent form (ICF) from the sponsor for a study closed to enrollment. Subjects are only in long-term follow-up. The change related to frequent radiation imaging at screening, with no change to drug safety profile. Who must the investigator notify first?

- A. No notification is required
- B. The IRB/IEC

- C. Sub-investigators
- D. Participants in long-term follow-up

Answer: B

Explanation:
* 21 CFR 56.109(a):IRBs must review all changes to informed consent before implementation.
* ICH E6(R2) 4.8.2:If new information could affect willingness to continue, consent forms must be revised and approved by the IRB.
Even though screening is closed, the IRB/IEC must review the updated form before any subject re-consenting.
References:21 CFR 56.109(a); ICH E6(R2) §4.8.2.

NEW QUESTION # 51
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. Staff training
- B. Adequate resources
- C. The protocol
- D. Proper equipment

Answer: C

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 # 52
A company's CEO wants to commercially promote a device under an IDE study. This plan:

- A. Requires IRB/IEC approval
- B. Would violate FDA regulations
- C. Requires IDE approval
- D. Requires a large advertising budget

Answer: B

Explanation:
* 21 CFR 812.7:Prohibits promotion of investigational devices or claiming safety/effectiveness until FDA approval is granted.
* Investigational devices may only be used in clinical trials, not marketed.
Thus, promotion during an IDE study is anFDA violation.
References:21 CFR 812.7.

NEW QUESTION # 53
During an audit for a Phase II IND study, the auditor identified unreported serious protocol deviations. Which party must take prompt action to ensure compliance?

- A. The investigator
- B. The IRB/IEC chair
- C. The sponsor
- D. The CRO

Answer: C

Explanation:
The sponsor holds ultimate responsibility for trial oversight and compliance.
* ICH E6(R2) 5.20.1:If noncompliance is discovered, the sponsor must "take prompt action to secure compliance" and, if necessary, terminate participation of the investigator/institution.
* 21 CFR 312.56(b):Sponsors must ensure proper conduct and report investigators who fail to comply to the FDA and IRB.
While investigators commit to protocol adherence, once deviations are identified,the sponsor must actto safeguard subjects and trial validity.
References:ICH E6(R2) §5.20.1; 21 CFR 312.56(b).

NEW QUESTION # 54
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