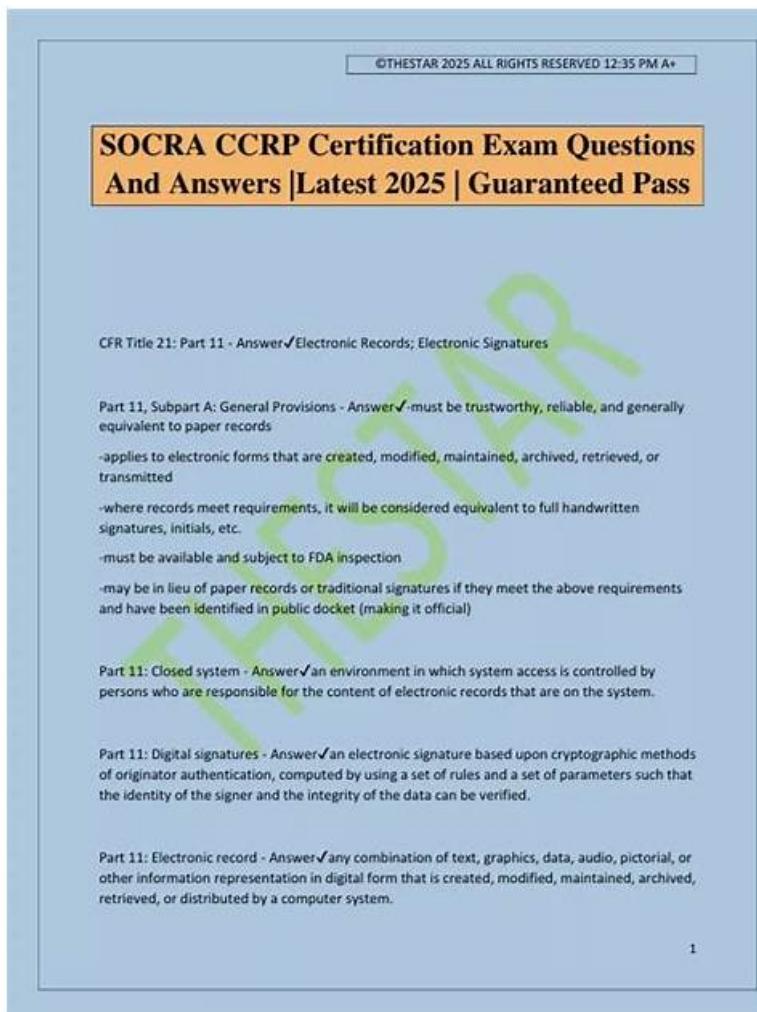


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CFR Title 21: Part 11 - Answer ✓ Electronic Records; Electronic Signatures

Part 11, Subpart A: General Provisions - Answer ✓ -must be trustworthy, reliable, and generally equivalent to paper records

- applies to electronic forms that are created, modified, maintained, archived, retrieved, or transmitted
- where records meet requirements, it will be considered equivalent to full handwritten signatures, initials, etc.
- must be available and subject to FDA inspection
- may be in lieu of paper records or traditional signatures if they meet the above requirements and have been identified in public docket (making it official)

Part 11: Closed system - Answer ✓ an environment in which system access is controlled by persons who are responsible for the content of electronic records that are on the system.

Part 11: Digital signatures - Answer ✓ 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.

Part 11: Electronic record - Answer ✓ 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.

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SOCRA CCRP Exam Syllabus Topics:

Topic	Details

Topic 1	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • 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 (Q63-Q68):

NEW QUESTION # 63

A clinical investigator is planning to conduct a quality of life medical device study in the United States. The study has been designed to comply with the approved indication for use of the device. In this situation, who must approve the investigator's proposed patient recruitment materials?

- A. The Office for Human Research Protections (OHRP)
- B. A scientific review board
- C. The FDA
- D. An IRB/IEC

Answer: D

Explanation:

Recruitment materials must be reviewed to protect subjects from misleading or coercive messaging.

* 21 CFR 56.111(a)(3):IRBs must ensure equitable subject selection.

* ICH E6(R2) 3.1.2:IRBs safeguard rights, safety, and well-being, including review of recruitment strategies.

FDA and OHRP do not approve recruitment materials; responsibility lies withIRB/IEC.

References:21 CFR 56.111(a)(3); ICH E6(R2) §3.1.2.

NEW QUESTION # 64

Which countries have officially adopted ICH-GCP E6(R2) as a standard, in addition to U.S., EU, Japan, Canada, and Australia?

- A. India
- B. Switzerland
- C. Brazil
- D. China

Answer: A

Explanation:

India has aligned national regulations with ICH-GCP.

* DCGI/ICMR Guidelines (India): Explicitly adopt ICH E6(R2) as part of its Good Clinical Practice standards. China and Brazil are harmonizing, but full official adoption is noted in India.

References: Indian GCP Guidelines (2017 revision).

NEW QUESTION # 65

An investigator received an updated investigator's brochure from the sponsor; the update did not include changes related to subject safety. Which of the following parties, if any, is the investigator required to notify?

- A. The Data Safety Monitoring Board (DSMB)
- B. **No notification is required**
- C. The regulatory authority
- D. The IRB/IEC

Answer: B

Explanation:

The Investigator's Brochure (IB) is updated by the sponsor to reflect new scientific or clinical information.

* ICH E6(R2) 7.3: "The sponsor should revise the IB as soon as new, significant information becomes available."

* ICH E6(R2) 4.1.5: Requires the investigator to ensure staff are informed, but there is no requirement to notify IRB/IEC unless subject safety, rights, or risk profile is affected.

Since this update contained no changes related to subject safety, the investigator is not obligated to notify IRB/IEC, DSMB, or regulators. The updated IB must simply be filed in the regulatory binder and implemented at the site.

Thus, the correct answer is D (No notification is required).

References:

ICH E6(R2), §7.3 (Updating the Investigator's Brochure).

ICH E6(R2), §4.1.5 (Investigator responsibilities for informing staff).

NEW QUESTION # 66

The sponsor of a multi-institutional clinical trial provided a site with information regarding a newly identified unanticipated adverse event attributed to study drug administration. The site's investigator has a subject actively receiving this study drug. Which of the following is the site investigator's responsibility to the subject?

- A. **To provide the subject with information regarding the significant new findings**
- B. To discontinue the subject's study drug
- C. To give the subject's contact information to the sponsor in order to allow the sponsor to contact the subject
- D. To submit this safety update to the regulatory authority

Answer: A

Explanation:

Investigators are obligated to inform subjects of new information that may affect their willingness to continue.

* ICH E6(R2) 4.8.2: "If new information becomes available that may be relevant to a subject's willingness to continue participation, the informed consent document should be revised, and the subject should be informed in a timely manner."

* 21 CFR 50.25(b)(5): Consent must include a statement that "significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided." Thus, the investigator must communicate new risk information to the subject.

Discontinuation (A) may not be warranted unless medically indicated. Reporting to FDA (B) is the sponsor's role. Sharing subject contact with sponsor (D) would violate confidentiality.

Correct answer:C.

References:

ICH E6(R2), §4.8.2.

21 CFR 50.25(b)(5).

NEW QUESTION # 67

In accordance with the Belmont Report, obtaining voluntary informed consent from subjects prior to enrolling them in a clinical trial is an example of which of the following ethical principles?

- A. Do no harm
- B. Beneficence
- C. Justice
- D. Respect for persons

Answer: D

Explanation:

The Belmont Report (1979) established three key ethical principles:

* Respect for Persons: Requires informed consent, recognition of autonomy, and protection of vulnerable individuals.

* Beneficence: Obligation to maximize benefits and minimize harm.

* Justice: Ensuring fairness in subject selection and distribution of research burdens/benefits.

Voluntary informed consent embodies Respect for Persons, as subjects are given adequate information and freedom of choice. "Do no harm" (A) is a Hippocratic principle but not Belmont terminology.

Thus, the correct answer is B (Respect for persons).

References:

The Belmont Report (1979), Part B: Basic Ethical Principles.

NEW QUESTION # 68

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