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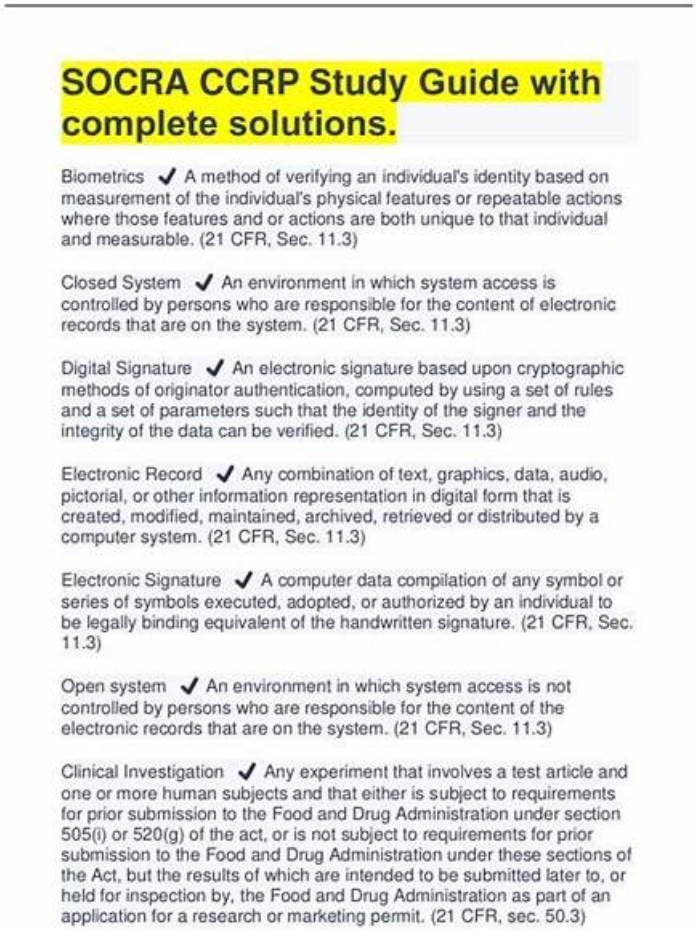
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Biometrics ✓ A method of verifying an individual's identity based on measurement of the individual's physical features or repeatable actions where those features and or actions are both unique to that individual and measurable. (21 CFR, Sec. 11.3)

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 Certified Clinical Research Professional (CCRP) Sample Questions (Q105-Q110):

**NEW QUESTION # 105**
On 15 May 2019, a sponsor announced that its investigational compound GHB33IA will not be investigated any further and will not be pursued for a marketing approval. According to the CFR, what is the earliest date when the site may begin to destroy the study records?

- A. 15 May 2022
- B. 15 May 2034
- C. 16 May 2021
- D. 16 May 2022

**Answer: D**

Explanation:
Record retention requirements ensure regulatory access to data even after development is discontinued.
* 21 CFR 312.62(c):"An investigator shall retain records... for2 years after the date a marketing application is withdrawn or discontinuedand FDA is notified."
* In this case, development was terminated15 May 2019. Therefore, the 2-year clock starts at discontinuation. Two years later is15 May 2021, but FDA requires records to be maintaineduntil after the 2-year period ends. Theearliest permissible destruction date is 16 May 2022 (C).
Options A and B are premature; D (2034) is far beyond requirements.
Thus, the correct answer isC (16 May 2022).
References:
21 CFR 312.62(c) (Investigator record retention).
21 CFR 312.57(c) (Sponsor record retention).

**NEW QUESTION # 106**
A study coordinator is preparing an IRB submission for a Phase II oncology study. Which document must be included?

- A. Record storage plan
- B. Case report forms
- C. Recruitment materials
- D. List of potential subjects

**Answer: C**

Explanation:
* ICH E6(R2) 3.1.2 & FDA Recruitment Guidance (1998):Recruitment materials must be reviewed by IRB to ensure no coercion or misleading claims.
* CRFs and storage plans are sponsor/site tools, not IRB-reviewed documents.
References:ICH E6(R2) §3.1.2; FDA Recruitment Guidance, 1998.

**NEW QUESTION # 107**
A subject enrolled in a drug clinical trial has withdrawn from the study. In accordance with ICH GCP, which of the following documents should be consulted to determine whether the participant should be replaced?

- A. The protocol
- B. The Investigator's Brochure
- C. The data safety monitoring plan

- D. The informed consent document

**Answer: A**

Explanation:
Theprotocolgoverns all trial conduct, including whether subjects should be replaced when they withdraw.
* ICH E6(R2) 6.0:The protocol must contain "detailed information on trial design, methodology, statistical considerations, and the organization of the trial."
* ICH E6(R2) 6.9.2:The section on "Subject withdrawal or discontinuation" specifies "whether and under what conditions subjects may be replaced." Other documents serve different functions: the DSM plan (A) manages safety oversight, the IB (C) summarizes product background, and the consent form (D) explains subject rights but does not guide study conduct. Only theprotocolprovides the operational answer regarding replacement.
Thus, the correct answer isB (The protocol).
References:
ICH E6(R2), §6.0 (Protocol content).
ICH E6(R2), §6.9.2 (Subject withdrawal/discontinuation).

**NEW QUESTION # 108**
Upon completion of a study, the investigator should do which of the following?

- A. Ensure that all payments from sponsor have been received
- B. Compile site data, publish the study results, and submit the publication to the IRB/IEC as the final report
- C. As soon as possible, provide the IRB/IEC with a final report that summarizes the trial's outcome
- D. Provide the IRB/IEC a final report, but only if the study has a positive outcome

**Answer: C**

Explanation:
Investigators must formally close out a trial with the IRB/IEC.
* ICH E6(R2) 4.13.2:"Upon completion of the trial, the investigator/institution should provide the IRB /IEC with a summary of the trial's outcome."
* 21 CFR 312.66:Reinforces investigator's duty to keep IRB informed throughout study lifecycle.
This applies regardless of whether outcomes were positive, negative, or inconclusive. IRBs are not concerned with sponsor payments (B) or publications (D).
Thus, the correct answer isA (Provide final report to IRB/IEC).
References:
ICH E6(R2), §4.13.2 (Final reporting requirement).

**NEW QUESTION # 109**
Which of the following identifies content that should be included in a clinical research protocol?

- A. IRB/IEC approval and meeting minutes
- B. Criteria for the selection of an investigator
- C. Standard operating procedures for data collection
- D. A summary of findings of nonclinical studies that potentially have clinical significance

**Answer: D**

Explanation:
Theprotocolmust provide scientific rationale, including prior nonclinical findings that justify human research.
* ICH E6(R2) 6.2.2:"The protocol should include... a summary of findings from nonclinical studies that potentially have clinical significance and from clinical trials that are relevant to the trial." Other listed options belong elsewhere:
* IRB approvals (A) are separate administrative records.
* SOPs for data collection (B) are sponsor-level procedural documents.
* Investigator selection (C) is a sponsor's responsibility, not protocol content.
Thus, the correct answer isD (Summary of nonclinical findings with clinical relevance).
References:
ICH E6(R2), §6.2.2 (Protocol contents).

**NEW QUESTION # 110**
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