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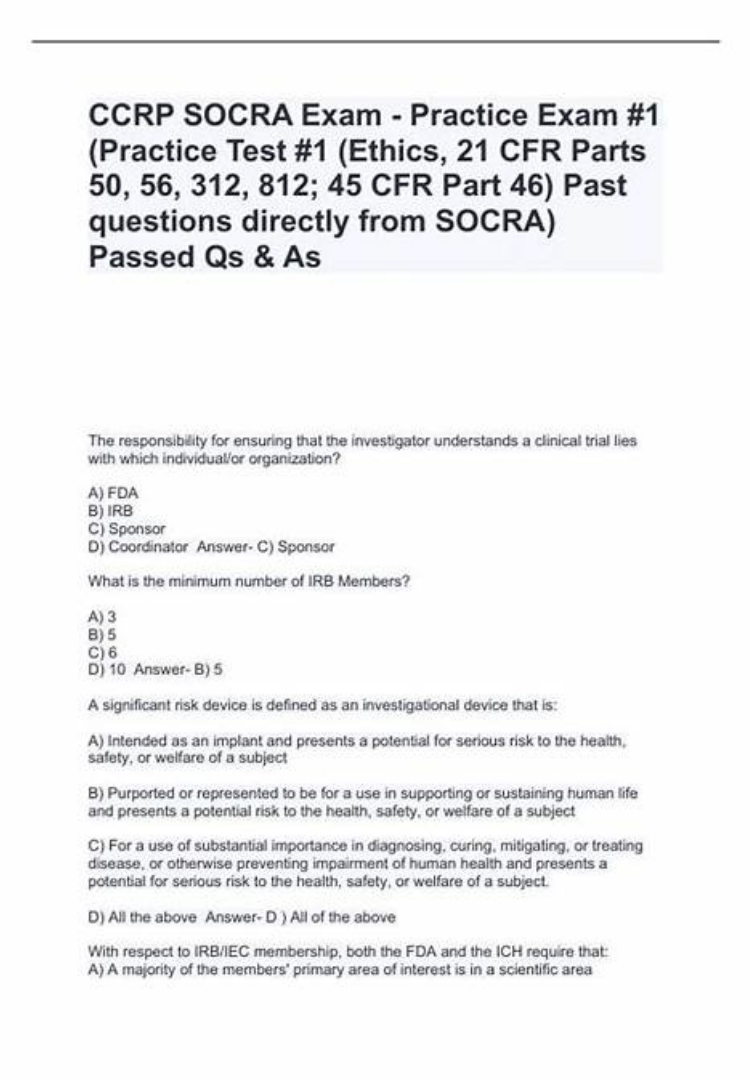
CCRP SOCRA Exam - Practice Exam #1 (Practice Test #1 (Ethics, 21 CFR Parts 50, 56, 312, 812; 45 CFR Part 46) Past questions directly from SOCRA) Passed Qs & As

The responsibility for ensuring that the investigator understands a clinical trial lies with which individual/or organization?

A) FDA
B) IRB
C) Sponsor
D) Coordinator Answer- C) Sponsor

What is the minimum number of IRB Members?

A) 3
B) 5
C) 6
D) 10 Answer- B) 5

A significant risk device is defined as an investigational device that is:

A) Intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject

B) Purported or represented to be for a use in supporting or sustaining human life and presents a potential risk to the health, safety, or welfare of a subject

C) For a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject.

D) All the above Answer- D) All of the above

With respect to IRB/IEC membership, both the FDA and the ICH require that:
A) A majority of the members' primary area of interest is in a scientific area

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions

(Q19-Q24):

NEW QUESTION # 19
In accordance with the CFR, the sponsor (who is not a sponsor-investigator) is responsible for which of the following?

- A. Ensuring that the FDA and all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug
- B. Overseeing the administration of the investigational drug to the subjects
- C. Submitting progress reports to the reviewing IRB/IEC
- D. Maintaining case histories that record all observations and other data pertinent to the investigation

Answer: A

Explanation:
Sponsors are responsible for distributing safety updates across all investigators and the FDA.
* 21 CFR 312.55(b):"The sponsor shall promptly notify all participating investigators, and the FDA, of new significant adverse effects or risks with respect to the drug." Other responsibilities fall elsewhere:
* Case histories (C) are maintained by investigators (21 CFR 312.62(b)).
* Progress reports to IRBs (D) are the investigator's duty (21 CFR 312.66).
* Administration of investigational drug (A) is managed by the investigator at site level.
Thus, the correct answer isB (Ensuring FDA and investigators are promptly informed).
References:
21 CFR 312.55(b) (Sponsor notification requirements).

NEW QUESTION # 20
In accordance with the ICH GCP Guideline, prior to initiating a trial, which of the following should define, establish, and allocate all trial-related duties and functions?

- A. The IRB/IEC
- B. The sponsor
- C. The institutional administrator
- D. The study coordinator

Answer: B

Explanation:
* ICH E6(R2) 5.2.1:"The sponsor is responsible for implementing and maintaining quality assurance and quality control systems... including allocation of trial-related duties."
* Although tasks may be delegated to CROs or site staff, accountability remains with thesponsor.
References:ICH E6(R2), §5.2.1.

NEW QUESTION # 21
After randomization, investigational drug is shipped to site. Who is responsible for accountability?

- A. Sponsor
- B. Investigational pharmacist
- C. Investigator
- D. Research coordinator

Answer: C

Explanation:
* ICH E6(R2) 4.6.1:"Responsibility for investigational product accountability at the trial site rests with the investigator."
* May delegate to pharmacist or coordinator, butultimate responsibilitylies with investigator.
References:ICH E6(R2) §4.6.1.

NEW QUESTION # 22

A monitor is conducting a site closeout visit. The study site kept electronic medical records and source documents in a system verified to be 21 CFR Part 11 compliant. The monitor reviewed all electronic documents by logging into the system with a unique login ID and password. In addition to the essential document file, which of the following sets of documents should be provided to the monitor during the study closeout visit?

- A. A copy of the final report for the IRB and investigational product shipment records
- B. Informed consent documents and printouts of electronic source documents
- C. Informed consent documents and investigational product documentation
- D. Printouts of electronic source documents and the remaining investigational product

Answer: C

Explanation:
During study closeout, the monitor verifies subject protection, protocol compliance, and investigational product accountability.
* ICH E6(R2) 8.1 & 8.4:Lists essential documents to be verified at closeout, including signed informed consent forms and investigational product accountability records.
* 21 CFR Part 11:Ensures electronic records are valid, so printed copies are not always necessary unless required for auditing.
Thus, the critical items for monitor review at closeout areinformed consent forms(to confirm subject protection) andinvestigational product documentation(to confirm reconciliation and disposition).
Correct answer:D.
References:
ICH E6(R2), §8.1, §8.4.

NEW QUESTION # 23
During an IND study closeout, a monitor discovered remaining investigational product. Which procedures must be followed for disposition?

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

Answer: A

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 # 24
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