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CCRP SOCRA Exam - Practice Exam 1 with Complete Solutions

NB: Answers to questions appear at the bottom of the choices and are highlighted in yellow

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

C) Sponsor

What is the minimum number of IRB Members?

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

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

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q15-Q20):

NEW QUESTION # 15

The sponsor withdrew an IND due to safety. Who must be notified promptly, in addition to FDA?

- A. Site coordinator
- **B. Reviewing IRBs/IECs**
- C. Investigational pharmacies
- D. OHRP

Answer: B

Explanation:

* 21 CFR 312.56(d): If an IND is withdrawn for safety, the sponsor must notify FDA and all participating investigators, who in turn notify IRBs.

* Ensures subjects are protected and sites stop enrollment.

References: 21 CFR 312.56(d).

NEW QUESTION # 16

A sponsor became aware of a new serious adverse event related to a drug. Who must be notified in addition to FDA?

- A. All investigational pharmacists
- B. All IRBs/IECs of record
- C. OHRP
- **D. All participating investigators**

Answer: D

Explanation:

* 21 CFR 312.32(c)(1)(ii): Sponsors must notify all participating investigators of any serious and unexpected suspected adverse reactions.

* Investigators then inform IRBs and subjects as appropriate.

References: 21 CFR 312.32(c)(1)(ii).

NEW QUESTION # 17

In accordance with the CFR and the ICH GCP Guideline, which of the following is directly responsible for submitting protocols and amendments to the IRB/IEC for review?

- A. The Food and Drug Administration
- **B. The investigator**
- C. The sponsor
- D. The contract research organization

Answer: B

Explanation:

The investigator bears direct responsibility for ensuring IRB/IEC review and approval before initiating a study or implementing any amendments.

* ICH E6(R2) 4.4.1: "Before initiating a trial, the investigator/institution should have written and dated approval/favorable opinion from the IRB/IEC for the trial protocol, written informed consent form, and any other written information to be provided to subjects."

* 21 CFR 312.66: "An investigator shall assure that an IRB that complies with the requirements... will be responsible for the initial and continuing review and approval of the proposed clinical study." While sponsors may provide protocol documents, the legal obligation to submit and maintain IRB/IEC approval rests with the investigator at each site. CROs act under sponsor delegation but cannot replace investigator accountability.

Thus, the correct answer is B (The investigator).

References:

ICH E6(R2), §4.4.1 (Investigator responsibilities).

21 CFR 312.66 (Investigator assurance of IRB oversight).

NEW QUESTION # 18

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

Answer: A

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 act to safeguard subjects and trial validity.

References: ICH E6(R2) §5.20.1; 21 CFR 312.56(b).

NEW QUESTION # 19

After the sponsor's auditor completes the final audit report for a Phase II trial with an investigational new drug, which of the following is responsible for providing the audit certificate to the clinical site?

- A. The regulatory authority
- B. The sponsor
- C. The IRB/IEC
- D. The Data Safety Monitoring Board

Answer: B

Explanation:

Audits are part of sponsor quality assurance to ensure trial compliance.

* ICH E6(R2) 5.19.3: "The sponsor's auditing procedures should include the provision of an audit certificate where required."

* ICH E6(R2) 8.2.20: Audit certificates are essential documents generated and retained by the sponsor.

IRBs (A), regulators (B), and DSMBs (C) are not responsible for audit documentation. Therefore, only the sponsor issues and maintains audit certificates, providing them to sites when appropriate.

Correct answer: D.

References:

ICH E6(R2), §5.19.3.

ICH E6(R2), §8.2.20.

NEW QUESTION # 20

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