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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q26-Q31):

NEW QUESTION # 26

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

Answer: A

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 with IRB/IEC.

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

NEW QUESTION # 27

According to ICH GCP, who besides the sponsor should approve the financial aspects of a clinical trial?

- A. DSMB
- B. Regulatory authority
- C. OHRP
- D. Investigator/institution

Answer: D

Explanation:

* ICH E6(R2) 5.6.1:"The sponsor should ensure agreement from the investigator/institution on the financial aspects of the trial."This ensures transparency in compensation, reimbursement, and budget.

References:ICH E6(R2) §5.6.1.

NEW QUESTION # 28

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

Answer: B

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 # 29

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 notifyall 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 # 30

In accordance with the CFR, clinical trial sponsors are required to retain records and reports after a marketing application is approved for at least:

- A. 15 years
- B. 3 years
- C. 5 years
- **D. 2 years**

Answer: D

Explanation:

The FDA record retention requirement for investigational drug studies is clearly outlined in 21 CFR 312.57 (c) and 21 CFR 312.62(c).

* 21 CFR 312.57(c): "A sponsor shall retain the records and reports... for 2 years after a marketing application is approved for the drug; or, if an application is not approved, until 2 years after shipment and delivery of the drug for investigational use is discontinued and FDA has been so notified."

* 21 CFR 312.62(c): Investigators also must retain study-related records for 2 years following the date a marketing application is approved or 2 years after the investigation is discontinued.

This requirement ensures FDA can audit investigational product data even after approval to confirm compliance and verify trial results. Longer retention (e.g., 15 years) may be institutional or sponsor policy but is not mandated by federal law.

Thus, the correct answer is A (2 years).

References:

21 CFR 312.57(c) (Sponsor record retention).

21 CFR 312.62(c) (Investigator record retention).

NEW QUESTION # 31

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