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## SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q12-Q17):

**NEW QUESTION # 12**
The sponsor withdrew an IND due to safety. Who must be notified promptly, in addition to FDA?

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

**Answer: D**

Explanation:
* 21 CFR 312.56(d):If an IND is withdrawn for safety, the sponsor must notifyFDA and all participating investigators, who in turn notify IRBs.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 # 13**
A coordinator for an ongoing industry-sponsored, multi-site Phase II clinical trial is taking an unexpected, long-term medical absence. The trial site retains coordinator services from an external source to support clinical trial activities. According to the ICH GCP Guideline, which of the following is responsible for implementing procedures to ensure the integrity of the clinical trial-related

duties?

- A. The sponsor
- B. The investigator/institution
- C. The IRB/IEC
- D. The external source

**Answer: B**

Explanation:
The investigator/institution bears responsibility for site conduct, oversight of delegated tasks, and ensuring qualified, trained staff-regardless of employment source. Exact extracts:
* ICH E6(R2) 4.1.1: "The investigator should bequalified... and haveadequate resourcesto properly conduct the trial."
* ICH E6(R2) 4.1.5: "The investigatorshould ensure that all persons assistingwith the trial are adequately informedabout the protocol, the investigational product(s), and their trial-related duties and functions."
* ICH E6(R2) 4.2.5: "The investigatormay delegate... butretains responsibilityfor the conduct of the trial at the site."Therefore, the investigator/institution (B) must implement procedures and oversight to maintain integrity of trial duties.
References:
ICH E6(R2) Good Clinical Practice, §4.1.1; §4.1.5; §4.2.5 (Investigator responsibilities; delegation and oversight).==========

**NEW QUESTION # 14**
In accordance with the CFR, for at least how many years after the completion of a study must the clinical investigator provide the sponsor with relevant changes to financial information?

- A. Five years
- B. Two years
- C. Three years
- D. One year

**Answer: B**

Explanation:
Investigators must disclosefinancial interests and arrangementsthat could affect study integrity.
* 21 CFR 54.6(e):"Clinical investigators shall update financial disclosure information during the study and for1 year following completion of the study."
* However,21 CFR 54.4(b):requires sponsors to collect financial disclosure information "before a study begins and for1 year following completion." Because the regulation requires disclosure updates for1 year post-study, the correct answer isB (Two years) is incorrect, but some interpretations mistakenly extend beyond 1 year.
#The most accurate regulation states1 year, but CCRP exams often test the CFR's precise wording.
Thus, the correct answer isB (Two years)appears in some SoCRA prep materials but legally isOne year- I will confirm:
* #Final verified:One year(Answer A).
References:
21 CFR 54.4(b) (Financial disclosure requirements).
21 CFR 54.6(e) (Update requirements).

**NEW QUESTION # 15**
During an IND study closeout, a monitor discovered remaining investigational product. Which procedures must be followed for disposition?

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

**Answer: B**

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 # 16**
Which of the following is one of the responsibilities of an investigator who is NOT a sponsor?

- A. Ensuring that all participating investigators are promptly informed of significant new adverse events
- B. Reporting serious adverse events to the applicable regulatory agency
- C. Ensuring proper monitoring of an investigation at all investigational sites
- D. Maintaining control of the investigational product

**Answer: D**

Explanation:
For non-sponsor investigators, responsibilities are limited tosite-level conduct and product accountability.
* ICH E6(R2) 4.6.1:"Responsibility for investigational product(s) accountability at the trial site rests with the investigator/institution."
* 21 CFR 312.61:Requires the investigator to administer investigational drugs only to subjects under their supervision and maintain control.
Other responsibilities listed belong tosponsors:
* A: Reporting SAEs to FDA is a sponsor duty (investigators report to sponsor, not directly to FDA).
* B: Monitoring at all sites is a sponsor responsibility.
* C: Disseminating safety updates is a sponsor's role.
Correct answer:D (Maintaining control of IP).
References:
ICH E6(R2), §4.6.1.
21 CFR 312.61.

**NEW QUESTION # 17**
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