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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q50-Q55):

NEW QUESTION # 50
What is included in the Statement of Investigator (Form FDA 1572)?

- A. A statement describing preclinical and human safety data
- B. A statement disclosing investigator financial interests
- C. A statement responding to FDA inspection observations
- D. A statement agreeing to comply with FDA regulations

Answer: D

Explanation:
FormFDA 1572is the investigator's signed agreement to follow regulations.
* 21 CFR 312.53(c)(1)(vi)(c):Requires investigators to sign Form 1572, committing to conduct trials in accordance withFDA regulations (21 CFR 50 & 56).
* The form includes commitments to personally supervise, obtain informed consent, maintain records, and permit FDA inspections.
It does not include financial disclosures (covered under21 CFR 54) or preclinical data (in theIB).
References:21 CFR 312.53(c)(1)(vi)(c).

NEW QUESTION # 51
Which of the following is one of the responsibilities of an investigator?

- A. Maintaining accurate and current case histories of study subjects
- B. Participating in the IRB/IEC voting process for approval of their protocol
- C. Updating the investigator brochure with new safety information
- D. Selecting qualified monitors on the basis of training, experience, and expertise

Answer: A

Explanation:
Investigators are required to maintain accurate subject records, often referred to ascase histories.
* 21 CFR 312.62(b):"An investigator shall prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation."
* ICH E6(R2) 4.9.0:Reinforces that investigators are responsible for recording, handling, and storing clinical trial data.
Incorrect options:
* B: Investigators may present protocols but cannot vote on IRB approval.
* C: Sponsor responsibility (ICH E6 §5.18).
* D: Sponsors are responsible for IB updates (ICH E6 §7.3.1).
Correct answer:A.
References:
21 CFR 312.62(b).
ICH E6(R2), §4.9.0.

NEW QUESTION # 52
In order to adequately monitor a clinical trial, the monitor must be familiar with each of the following, EXCEPT the:

- A. Requirements for storage of the investigational product
- B. IRB/IEC requirements for reporting to the regulatory authority
- C. Written information to be provided to the subjects
- D. Sponsor's SOPs

Answer: B

Explanation:
Monitors verify compliance with protocol, sponsor SOPs, GCP, and regulations.
* ICH E6(R2) 5.18.4:Outlines monitor responsibilities, including verifying informed consent, protocol compliance, investigational product accountability, and adherence to sponsor SOPs.
* Monitors must also be familiar with subject-facing documents (A) and storage requirements for investigational product (B).
However,IRB/IEC requirements for reporting to regulatory authoritiesare outside a monitor's scope.
That responsibility lies with investigators and IRBs under21 CFR 56.108(b).
Thus, the correct answer isD.
References:
ICH E6(R2), §5.18.4.
21 CFR 56.108(b).

NEW QUESTION # 53
A Phase I clinical trial is initiating. Who is responsible for ensuring that site staff are adequately informed about trial duties?

- A. Clinical investigator
- B. Program manager
- C. IRB/IEC
- D. Sponsor

Answer: A

Explanation:
* ICH E6(R2) 4.2.4:"The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, investigational product, and trial-related duties."This responsibility cannot be delegated to sponsor or IRB.
References:ICH E6(R2), §4.2.4.

NEW QUESTION # 54
Which of the following is an example of an additional protection required when conducting research on children?

- A. The investigator must obtain age-appropriate assent as determined by the IRB/IEC
- B. There must be an impartial advocate present during the consent process
- C. Parents must be present during all procedures
- D. The study must be approved by a central pediatric IRB

Answer: A

Explanation:
Children are a vulnerable population. U.S. regulations require IRB/IEC judgment about when and howassent is obtained, in addition to parental permission. Exact extracts:
* 45 CFR 46.408(a): "The IRB shall determine...whether and to what extent children are capable of providing assent."
* ICH E6(R2) 4.8.12: "Where a subject is unable to give consent personally,assent should be obtained when appropriate, in accordance with applicable regulatory requirement(s)."Thus, the additional protection is IRB-determined, age-appropriate assent (B). Options A, C, and D are not universal requirements for all pediatric research.
References:
ICH E6(R2) Good Clinical Practice, §4.8.12 (Informed consent/assent).
45 CFR 46 Subpart D-Additional Protections for Children, §46.408(a).==========

NEW QUESTION # 55
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