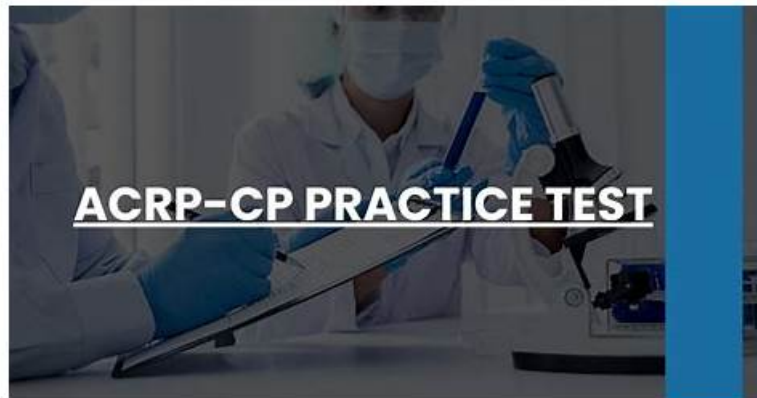


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ACRP Certified Professional Exam Sample Questions (Q44-Q49):

NEW QUESTION # 44

Confidentiality and privacy rules for protection of human subjects at research sites are determined by the:

- A. PI
- B. Sponsor
- C. Applicable site SOPs
- D. Applicable regulatory authorities

Answer: D

Explanation:

The confidentiality and privacy rules protecting human subjects in clinical research are established by applicable regulatory authorities, such as the FDA or EMA, and must be followed by all research sites. These regulations ensure that participants' personal data are handled securely and ethically.

GCP guidelines mandate compliance with local, national, and international regulations regarding data confidentiality and privacy.

"Confidentiality and privacy protections are determined by applicable regulatory authorities and must be adhered to by all study sites." Objectives:

* Protect participant privacy.

* Ensure compliance with data protection regulations.

NEW QUESTION # 45

Upon receipt of temperature-controlled IP, the study staff noticed the IP incurred a temperature excursion during transport. What should the staff do NEXT?

- A. Dispose of IP and request replacement from sponsor.
- **B. Register IP in IWRS, quarantine and notify sponsor of the excursion.**
- C. Register IP in IWRS and continue with subject allocation.
- D. Quarantine IP without registering in IWRS and request replacement from sponsor.

Answer: B

Explanation:

If a temperature-controlled IP has experienced a temperature excursion during transport, the appropriate action is to register the IP in the Interactive Web Response System (IWRS), quarantine it to prevent use, and immediately notify the sponsor. This procedure ensures that the IP is not used until the sponsor evaluates its stability and suitability.

GCP guidelines state that any IP affected by a temperature excursion should be quarantined and reported to the sponsor for evaluation.

"Upon identification of a temperature excursion, the IP must be quarantined and reported to the sponsor to determine its usability."

Objectives:

- * Maintain IP integrity and compliance with storage conditions.
- * Follow protocol for managing temperature excursions.

NEW QUESTION # 46

Who on the local site research study team is accountable for the unblinding documentation of IP?

- **A. PI**
- B. Pharmacist
- C. Regulatory manager
- D. CRC

Answer: A

Explanation:

The Principal Investigator (PI) is ultimately responsible for maintaining and documenting any unblinding events related to the investigational product (IP). This accountability ensures that any instance where the blind is broken is properly justified, documented, and reported to maintain trial integrity.

GCP guidelines state that the PI must oversee the unblinding process and ensure proper documentation to protect the validity of the trial data.

"The PI is responsible for ensuring that any unblinding of the investigational product is adequately documented and reported according to protocol." Objectives:

- * Maintain the integrity of blinded studies.
- * Properly document unblinding incidents.

NEW QUESTION # 47

A new device trial is being considered. Before committing to participate in the trial, what is the MOST important item the PI needs to evaluate?

- A. Information to be included in the advertising flyer
- **B. Availability of qualified staff to conduct the trial**
- C. Location of stored trial records
- D. Length of time to receive the approved trial device

Answer: B

Explanation:

The availability of qualified staff to conduct the trial is essential for maintaining compliance with protocol requirements and ensuring

patient safety. Without adequately trained and available staff, the trial's integrity and data quality are compromised. This answer is based on GCP guidelines emphasizing the importance of having trained and qualified personnel before initiating a trial. "The PI must ensure that sufficient qualified staff is available to conduct the trial as per the protocol and regulatory requirements." Objectives:

- * Assessing resource availability
- * Ensuring readiness to initiate a clinical trial

NEW QUESTION # 48

Centralized monitoring can:

- A. Identify IP accountability and storage issues.
- B. Enable appropriate stratification of subject enrollment.
- C. Confirm why sites are deviating from the protocol.
- D. Indicate the need to send monitors to perform onsite visits.

Answer: D

Explanation:

Centralized monitoring involves the remote evaluation of data trends, outliers, and inconsistencies across sites. If significant issues are identified through centralized monitoring, it may prompt the need for targeted on-site visits to investigate and resolve the identified issues. This approach optimizes resource utilization and focuses on potential problem areas.

GCP guidelines support the use of centralized monitoring to identify risks that warrant on-site monitoring, promoting efficient and targeted oversight.

"Centralized monitoring can identify data patterns or anomalies that indicate the need for an on-site visit to verify and address the issue." Objectives:

- * Enhance monitoring efficiency through data-driven decisions.
- * Prioritize on-site visits based on identified risks.

NEW QUESTION # 49

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