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ACRP CP PRACTICE Questions and Answers 100% Correct | Updated 2023-2024

What would be the first priority for an investigator when a subject wishes to withdraw prematurely from the trial? - Answer Try to obtain the subject's reason for withdrawal.

CRO recently switched from paper CRF to an EDC system. The EDC system must conform to the established requirements for: - Answer Validation, accuracy, reliability, completeness.

Part of a sponsor's responsibility pertaining to electronic trial data handling is to - Answer maintain an audit trail, data trail, and edit trail.

A research subject's responsibilities for study participation should be described in the: - Answer ICF

What document would an investigator reference to learn more about the previous clinical and nonclinical results of studies of the IP? - Answer Investigators brochure

During a multi site clinical study, whose responsibility is it to report subject recruitment rate? - Answer The CRA

An unconscious adult subject was enrolled in a study after obtaining consent from an LAR, and protocol therapy was initiated. The subject showed significant improvement in his clinical condition, and regained consciousness. The Investigator should inform the subject about the study and - Answer Obtain consent from the subject for the study

A site is in the start up phase of an industry sponsored phase 3 trial, and has received IRB approval. The site can begin enrolling subjects after... - Answer A signed clinical trial agreement between the site and sponsor is in place

A site is screening potential subjects for a study looking at mild cognitive impairment. One of the inclusion criteria is a score of 25 or less on a psychometric test, a research specific tool which measures

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ACRP Certified Professional Exam Sample Questions (Q62-Q67):

NEW QUESTION # 62

What would a sponsor use to implement and maintain quality in a study?

- A. Clinical trial agreement
- B. Statistical analysis plan
- C. Protocol signature pages
- D. Standard operating procedures

Answer: D

Explanation:

Standard Operating Procedures (SOPs) are essential for implementing and maintaining quality in a clinical study. SOPs outline the standardized methods for conducting study-related tasks, ensuring consistency, compliance, and quality across all trial sites. They are critical for training personnel, guiding the conduct of study activities, and maintaining protocol adherence.

GCP guidelines state that sponsors must develop and maintain SOPs to ensure the quality and consistency of clinical trial processes. "The sponsor should establish SOPs to maintain the quality of clinical trials, covering all aspects of trial conduct, data handling, and safety management." Objectives:

- * Ensure consistent and high-quality trial conduct.
- * Standardize procedures across trial sites.

NEW QUESTION # 63

All site financial matters pertaining to a trial are listed in what document?

- A. Financial disclosure
- B. Informed consent form
- C. Protocol
- D. Signed contract

Answer: D

Explanation:

All financial agreements, including compensation, budgeting, and payment terms related to the conduct of a clinical trial, are documented in the signed contract between the sponsor and the site. This contract outlines the financial responsibilities and ensures transparency and compliance.

GCP guidelines stipulate that financial matters related to the conduct of a trial are to be formally documented in contractual agreements.

"The financial aspects of a clinical trial must be outlined in the signed agreement between the sponsor and the site, ensuring clear understanding of compensation and obligations." Objectives:

- * Ensure financial transparency and accountability.
- * Maintain compliance with contractual obligations.

NEW QUESTION # 64

A site has reported multiple temperature excursions for an IP, primarily because the air conditioning (A/C) gets shut off after business hours. A separate A/C unit cannot be installed in the room where the IP is kept.

What would be the MOST effective long-term mitigation strategy?

- A. Invest in a room temperature controlled IP cabinet and transfer IP to this unit.
- B. Continue reporting temperature excursions per the pharmacy manual guidelines.

- C. Install an air cooler requiring regular water refills to maintain the room temperature.
- D. Return all IP and request the CRO/Sponsor to directly ship IP to participants.

Answer: A

Explanation:

Investing in a temperature-controlled IP cabinet is the most effective and sustainable solution for maintaining IP stability. This cabinet can consistently regulate temperature without relying on external A/C systems, thereby minimizing the risk of excursions and ensuring compliance with storage requirements.

GCP guidelines state that IP must be stored under controlled conditions as specified by the protocol and product labeling. "Temperature-controlled storage units should be used when site environmental conditions are not reliable to maintain IP stability."

Objectives:

- * Ensure IP stability and compliance.
- * Mitigate temperature excursion risks effectively.

NEW QUESTION # 65

Who determines the age of assent for pediatric studies?

- A. PI
- B. Parent
- C. IRB/IEC
- D. Sponsor

Answer: C

Explanation:

The IRB/IEC determines the age at which a child is considered capable of providing assent for participation in a clinical trial. This decision is based on local regulations, cultural considerations, and the child's ability to understand the trial's risks and benefits. The age of assent may vary between jurisdictions and is subject to ethical considerations specific to pediatric research.

GCP guidelines emphasize that the IRB/IEC is responsible for setting the criteria for obtaining assent from minors based on ethical and regulatory frameworks.

"The IRB/IEC is responsible for determining the age and circumstances under which pediatric assent is required, considering the child's comprehension level." Objectives:

- * Ensure appropriate ethical practices in pediatric research.
- * Align with local regulatory requirements for assent.

NEW QUESTION # 66

Who should vote during the IRB/IEC review and discussion process?

- A. All IRB/IEC members and non-member experts
- B. All IRB/IEC members
- C. All members who were involved in the review and discussion and non-member experts
- D. All members who were involved in the review and discussion

Answer: D

Explanation:

During the IRB/IEC review process, only members who actively participated in the review and discussion are eligible to vote. This ensures that votes are cast by those who are adequately informed about the study and can make an educated decision. Non-member experts may participate in discussions but do not have voting rights.

GCP guidelines state that voting rights in IRB/IEC meetings are limited to members who have thoroughly reviewed and discussed the study, maintaining unbiased and informed decision-making.

"Only IRB/IEC members who were involved in the review and discussion should participate in the voting process." Objectives:

- * Ensure informed voting in ethical review processes.
- * Maintain integrity and objectivity in IRB/IEC decisions.

NEW QUESTION # 67

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