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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 (Q18-Q23):

NEW QUESTION # 18

Which of the following should be considered when implementing a risk-based monitoring plan?

- A. On-site monitoring frequency may change depending on the quality of the data.
- B. Monitoring schedule must be pre-defined in the monitoring plan.
- C. 100% source document review is mandatory.
- D. Centralized monitoring must be incorporated in any trials.

Answer: A

Explanation:

Risk-based monitoring focuses on adapting the frequency and intensity of on-site visits based on data quality and site performance. If the data is consistently accurate and reliable, the monitoring frequency may be reduced. Conversely, if issues are identified, more frequent monitoring may be necessary.

GCP guidelines emphasize a flexible approach to monitoring, allowing adjustments based on the risk profile and quality of data collected.

"Risk-based monitoring involves adapting the frequency of on-site visits according to the quality of the data and the site's compliance level." Objectives:

- * Implement a dynamic monitoring strategy.
- * Enhance efficiency while maintaining data integrity.

NEW QUESTION # 19

A study subject inadvertently disposed of IP medication bottles. The site should report this to the:

- A. Sponsor.
- B. IRB/IEC.
- C. Regulatory authority.
- D. Medical monitor.

Answer: A

Explanation:

The loss or disposal of investigational product (IP) must be reported to the sponsor. The sponsor will evaluate the situation and determine the next steps, including whether additional reporting to regulatory authorities or corrective actions are necessary.

Reporting to the sponsor ensures that the accountability of the IP is properly documented and managed.

GCP guidelines specify that any loss or disposal of IP should be immediately reported to the sponsor for appropriate action and documentation.

"Any incident involving the loss, mishandling, or disposal of IP should be reported to the sponsor to maintain accurate drug accountability." Objectives:

- * Maintain accurate IP accountability.
- * Comply with sponsor requirements for IP management.

NEW QUESTION # 20

Which document confirms the PI's agreement to permit auditing at the study site?

- A. ICF
- B. IB
- C. Protocol
- D. Delegation Log

Answer: A

Explanation:

The Informed Consent Form (ICF) typically includes a statement indicating that the participant's records may be reviewed by monitors, auditors, and regulatory authorities. This ensures transparency and compliance with regulatory requirements, allowing for audits and inspections when necessary.

This answer follows GCP guidelines which specify that the ICF should include consent for audits and inspections to protect subject confidentiality while ensuring data integrity.

"The ICF must include a statement allowing access to trial data for monitoring, auditing, and regulatory inspection purposes."

Objectives:

- * Ensure informed consent for data access.
- * Facilitate compliance with auditing requirements.

NEW QUESTION # 21

When determining whether a protocol deviation (PD) is reportable to the IRB/IEC, the PI should take into consideration whether the:

- **A. PD affected participant safety.**
- B. Participant verbally agreed to the PD.
- C. PD affected participant recruitment.
- D. Sponsor approved the PD.

Answer: A

Explanation:

The primary factor in determining whether a protocol deviation should be reported to the IRB/IEC is whether the deviation impacts participant safety or the integrity of the study data. Any deviation that could pose a risk to participants must be reported promptly to ensure ongoing ethical oversight.

GCP guidelines mandate reporting of any protocol deviations that affect safety or data integrity to the IRB/IEC.

"Protocol deviations that impact the safety of participants or the integrity of the study must be reported to the IRB/IEC." Objectives:

- * Maintain participant safety.
- * Ensure regulatory compliance through prompt reporting.

NEW QUESTION # 22

A site is starting up a Phase III trial. They have received IRB/IEC approval and have scheduled the SIV. The site cannot begin enrolling subjects until:

- A. The site receives approval from the medical monitor to begin enrolling.
- B. The DSMB meets and the first DSMB meeting report has been issued.
- C. The CRA has performed source document review and verification at the site.
- **D. A signed clinical trial agreement between the site and sponsor is in place.**

Answer: D

Explanation:

Before a clinical trial site can begin enrolling participants, there must be a signed clinical trial agreement (CTA) between the site and the sponsor. This agreement outlines the responsibilities, financial arrangements, and expectations between both parties, ensuring that the trial is conducted in compliance with regulatory and ethical standards.

GCP guidelines require that a formal agreement be in place before trial initiation to protect the rights and obligations of both the sponsor and the site.

"Before subject enrollment can commence, the sponsor and site must finalize a clinical trial agreement, establishing legal and ethical commitments." Objectives:

- * Ensure proper contractual arrangements before trial initiation.
- * Protect legal rights and obligations of involved parties.

NEW QUESTION # 23

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