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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 (Q69-Q74):

NEW QUESTION # 69

IP is dispensed to all subjects who:

- A. Consented for the trial.
- B. Screened for the trial.
- C. Are eligible to receive it in the trial.
- D. Need IP for their medical condition.

Answer: C

Explanation:

The investigational product (IP) is only dispensed to subjects who meet the eligibility criteria as defined in the study protocol. Eligibility is confirmed during screening and baseline assessments. Simply consenting to the trial does not guarantee receipt of IP. According to GCP guidelines, IP dispensing must strictly follow eligibility criteria to maintain protocol compliance and subject safety. "IP should only be dispensed to subjects who have been deemed eligible according to the protocol's inclusion and exclusion criteria."

Objectives:

- * Maintain adherence to protocol criteria.
- * Protect participant safety by ensuring proper eligibility.

NEW QUESTION # 70

The objective of a randomized clinical trial is to look at whether an IP is effective in preventing recurrence of a disease. What would be a possible primary endpoint of the trial?

- A. Occurrence of known side effects of the IP
- B. Time to occurrence of symptoms of the disease
- C. Impact of an approved vaccine against the disease
- D. Use of concomitant medications to treat the symptoms

Answer: B

Explanation:

In a clinical trial aimed at assessing whether an IP prevents disease recurrence, the primary endpoint would typically be the "time to occurrence of symptoms" indicating a relapse or recurrence. This endpoint directly measures the IP's effectiveness in prolonging the symptom-free period.

This answer follows the GCP guideline, which states that primary endpoints should directly reflect the trial's objectives, particularly when evaluating recurrence prevention.

"In trials evaluating recurrence prevention, the primary endpoint should measure the time until recurrence of the target symptoms or condition." Objectives:

- * Assess the efficacy of IP in preventing disease recurrence.
- * Accurately measure the time to recurrence as a primary endpoint.

NEW QUESTION # 71

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. A signed clinical trial agreement between the site and sponsor is in place.
- C. The CRA has performed source document review and verification at the site.
- D. The DSMB meets and the first DSMB meeting report has been issued.

Answer: B

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 # 72

A hospital site is being considered for a trial that requires the IP refrigerator to be continuously monitored using the sponsor-provided Wi-Fi-enabled thermometer. The hospital's Wi-Fi connectivity is inconsistent.

During site selection, how should the CRA proceed?

- A. Before accepting this site, ensure the refrigerator is calibrated and functioning properly.
- **B. Before accepting this site, report the risk to the trial sponsor and await their decision.**
- C. Accept this site and plan to undertake routine safety evaluations of the IP.
- D. Accept this site and implement and maintain QA and QC systems with written SOPs.

Answer: B

Explanation:

Since the Wi-Fi connectivity is inconsistent, the CRA must assess the risk and report it to the trial sponsor for a decision. Accepting the site without proper risk evaluation may compromise the monitoring of the investigational product (IP) storage conditions, affecting trial integrity.

The answer follows GCP guidelines that emphasize assessing potential risks during site selection and involving the sponsor when critical issues arise.

"When faced with site-specific issues that may affect data integrity or product safety, the CRA should consult with the sponsor before making a final decision." Objectives:

- * Ensuring proper site selection
- * Managing potential risks proactively

NEW QUESTION # 73

A deferred consent can take place in which of the following situations?

- A. Only when the PI approves such a consent process immediately prior to patient enrollment, regardless of the situation being classed as emergency.
- **B. In an emergency situation only, when this process is described in the protocol and has received permission from the ethics committee.**
- C. In an emergency situation only, even when this process is not described in the protocol, but the sponsor approves the consent process.
- D. Only when the PI approves such a consent process, regardless of the emergency situation described in the protocol.

Answer: B

Explanation:

Deferred consent is permissible in emergency situations where immediate intervention is necessary and obtaining prior consent is not feasible. However, this practice must be explicitly described in the protocol and approved by the ethics committee. This ensures that the rights of patients are protected even in urgent circumstances.

GCP guidelines emphasize that deferred consent is only allowed when pre-approved by the ethics committee as part of the protocol for emergency interventions.

"In emergencies, deferred consent is permitted only if outlined in the protocol and approved by the ethics committee, ensuring compliance with ethical standards." Objectives:

- * Protect patient rights in emergency research.
- * Ensure ethical approval for deferred consent.

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