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ACRP Certified Professional Exam Sample Questions (Q41-Q46):

NEW QUESTION # 41

A trial subject was involved in a traffic accident. The emergency room (ER) doctor notifies the investigator that he wants to give the subject a blood transfusion. Blood transfusion is one of the prohibited treatments in the trial. How should the investigator respond?

- A. Advise the ER doctor to transfuse the blood, and the PI should report this incident to the sponsor.
- B. Report this incident immediately to the sponsor and leave the treatment decision to them.
- C. Advise the ER doctor to transfuse blood, and the PI should withdraw the subject from the trial.
- D. Ask the ER doctor not to transfuse blood and consider another treatment compliant with the protocol.

Answer: A

Explanation:

The investigator must prioritize the subject's immediate health and safety. In a medical emergency, the appropriate response is to advise the ER doctor to proceed with the necessary medical intervention (blood transfusion). Afterward, the PI must promptly report the incident to the sponsor as a protocol deviation.

GCP guidelines emphasize that patient safety takes precedence over protocol requirements in emergency situations.

"In situations where immediate medical intervention is necessary to prevent harm, the investigator should ensure that the appropriate care is given and subsequently report the event as a deviation." Objectives:

- * Prioritize patient safety in emergencies.
- * Report protocol deviations promptly.

NEW QUESTION # 42

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

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

Answer: C

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 # 43

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

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

Answer: C

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 # 44

A protocol inclusion criterion requires the serum magnesium at screening to be within the normal range. After the subject received IP, the CRC discovers the subject's screening magnesium level was below the normal range and the sub-investigator marked the lab sheet as not clinically significant. Which of the following should be done FIRST?

- A. Notify the subject.
- **B. Notify the sponsor.**
- C. Notify the regulatory authority.
- D. Withdraw the subject.

Answer: B

Explanation:

When a protocol deviation is identified, especially one involving inclusion criteria, the sponsor must be notified immediately. The sponsor will assess the deviation and determine whether the subject can continue in the study. Early notification ensures appropriate action and compliance with protocol and regulatory guidelines.

This answer aligns with GCP principles that mandate sponsor notification in case of protocol deviations, especially when they may impact participant safety or data integrity.

"Any deviation from the protocol that affects subject eligibility must be reported to the sponsor immediately for evaluation and guidance." Objectives:

- * Maintain adherence to protocol inclusion criteria.
- * Report deviations promptly for safety assessment.

NEW QUESTION # 45

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

Answer: A

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 # 46

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