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ACRP Certified Professional Exam Sample Questions (Q101-Q106):

NEW QUESTION # 101

A monitor identifies multiple deviations from a protocol-defined timeline for study procedures. The monitor is unable to identify proof of PI review and assessment of the deviations. The monitor discusses the deviations with the PI, who initiates a CAPA. What is the purpose of this CAPA?

- A. To determine if the deviations invalidate the data
- **B. To establish a procedure for PI oversight of protocol deviations**
- C. To determine if a protocol amendment is needed
- D. To escalate corrective actions to the regulatory authority

Answer: B

Explanation:

A Corrective and Preventive Action (CAPA) plan is implemented to address deviations and prevent them from recurring. In this context, the purpose of the CAPA is to establish a procedure for the Principal Investigator (PI) to ensure proper oversight of protocol deviations. This ensures that all future deviations are appropriately managed, reviewed, and documented according to GCP standards.

The answer is verified from GCP guidelines which emphasize that CAPA should focus on identifying root causes and establishing processes to prevent future deviations.

"A CAPA plan must address the root cause and implement systematic actions to prevent the recurrence of protocol deviations."

Objectives:

- * Ensuring PI oversight in protocol adherence
- * Maintaining data integrity through systematic corrective actions

NEW QUESTION # 102

Who is responsible for submitting a protocol amendment to the IRB/IEC?

- **A. Investigator**
- B. CRC
- C. CRA
- D. Sponsor

Answer: A

Explanation:

The investigator holds the responsibility for submitting any protocol amendments to the IRB/IEC for review and approval. This step ensures that all changes are ethically evaluated before being implemented, maintaining compliance with regulatory requirements. According to GCP guidelines, the investigator must submit protocol changes to the IRB/IEC to secure approval before making any modifications to the study.

"The investigator must inform the IRB/IEC of any proposed protocol changes and secure approval prior to implementation."

Objectives:

- * Maintain ethical oversight in study modifications.
- * Adhere to regulatory submission requirements.

NEW QUESTION # 103

Which strategy is used to safeguard subject privacy?

- A. Email updated enrollment logs to the CRA.
- B. Store source documentation in the CRC's office.
- **C. Conduct subject-related conversations in controlled environments.**
- D. Utilize subject initials on correspondence.

Answer: C

Explanation:

Conducting subject-related conversations in controlled environments ensures that personal and sensitive information is not overheard or disclosed to unauthorized individuals. This practice upholds patient confidentiality as required by GCP and data protection regulations.

The answer follows GCP guidelines for protecting the privacy and confidentiality of clinical trial participants.

"Conversations regarding study subjects should be held in secure and controlled environments to protect personal data." Objectives:

- * Ensuring confidentiality in clinical trial settings.
- * Protecting patient privacy according to ethical standards.

NEW QUESTION # 104

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

- A. All IRB/IEC members and non-member experts
- B. All members who were involved in the review and discussion and non-member experts
- C. All IRB/IEC members
- **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 # 105

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

- A. Informed consent form
- B. Protocol
- C. Financial disclosure
- **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 # 106

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