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ACRP Certified Professional Exam Sample Questions (Q46-Q51):

NEW QUESTION # 46
Access to study documentation for auditors and inspectors during an audit or inspection at a clinical trial site is the responsibility of the:

- A. CRC
- B. CRA
- C. PI

- D. Sponsor

Answer: C

Explanation:
The Principal Investigator (PI) is responsible for providing access to study documentation during an audit or inspection. This includes regulatory files, participant records, and study logs. The PI ensures that auditors and inspectors have appropriate access while maintaining the confidentiality of subject data.
GCP guidelines clearly assign the responsibility for maintaining and granting access to trial documentation to the PI at the study site.
"The PI is responsible for ensuring that study-related documents are available for review during audits or inspections." Objectives:
* Maintain transparency during inspections.
* Ensure compliance with documentation requirements.

NEW QUESTION # 47
The IRB/IEC has decided to not approve a clinical trial. Who must they notify in writing?

- A. Regulatory Agency
- B. CRC
- C. PI
- D. Sponsor

Answer: C

Explanation:
When the IRB/IEC decides not to approve a clinical trial, they must notify the Principal Investigator (PI) in writing. This communication ensures that the PI is formally informed of the decision and cantake appropriate actions, such as revising the protocol or addressing the reasons for disapproval.
According to GCP guidelines, the IRB/IEC must communicate any decision regarding the approval status of a study directly to the PI, as the PI is responsible for the conduct of the trial.
"The IRB/IEC should promptly notify the investigator in writing of its decision to approve or disapprove the proposed research activity." Objectives:
* Maintain clear communication between the IRB/IEC and the investigator.
* Ensure timely notification of decisions affecting the study.

NEW QUESTION # 48
Who on the local site research study team is accountable for the unblinding documentation of IP?

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

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 # 49
After the completion or termination of a clinical trial, who should store the enrollment log?

- A. Regulatory authority
- B. PI
- C. CRO
- D. Sponsor

Answer: B

Explanation:
The Principal Investigator (PI) is responsible for maintaining and securely storing essential documents, including the enrollment log, after the completion or termination of a clinical trial. This ensures that all participant-related records are retained for audit or inspection as per regulatory requirements.
This answer is consistent with GCP guidelines, which specify that the PI is accountable for retaining essential trial documents at the study site.
"The investigator should maintain records of trial participants, including the enrollment log, as part of the essential documents for trial conduct." Objectives:
* Maintain data integrity and compliance with record-keeping requirements.
* Ensure secure and accessible storage of participant information.

NEW QUESTION # 50
Which of the following activities would be undertaken by the sponsor to BEST ensure overall quality of the study data?

- A. Ensure submission of a data management plan to the regulatory authorities.
- B. Conduct annual reviews of the protocol and accompanying study documents.
- C. Ensure there is an accompanying written record that describes the consent process.
- D. Develop a plan that describes the monitoring approach for a clinical study.

Answer: D

Explanation:
Developing a monitoring plan that outlines the approach to quality assurance is essential for maintaining data integrity throughout the clinical trial. This plan helps identify critical data points, risk-based monitoring strategies, and procedures for detecting and correcting data discrepancies. It ensures that the study data collected is accurate, complete, and verifiable.
GCP guidelines emphasize the importance of a monitoring plan to safeguard the quality and integrity of study data.
"The sponsor should develop a comprehensive monitoring plan to ensure the accuracy, completeness, and consistency of trial data."
Objectives:
* Maintain high-quality data through structured monitoring.
* Identify potential risks and address them proactively.

NEW QUESTION # 51
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