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ACRP Certified Professional Exam Sample Questions (Q52-Q57):

NEW QUESTION # 52

Which strategy is used to safeguard subject privacy?

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

Answer: A

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 # 53

A written description of a trial in which the clinical and statistical description, presentations, and analyses are fully integrated into a single document is called a:

- A. IDMC/DSMB Report
- B. Investigator Brochure
- **C. Clinical Study Report**
- D. Clinical Study Protocol

Answer: C

Explanation:

A Clinical Study Report (CSR) is a comprehensive document that integrates clinical and statistical data from a clinical trial. It provides a complete and detailed account of the study's methods, results, and conclusions, including safety and efficacy analyses.

The CSR is prepared at the end of the trial to summarize the data for regulatory submission and scientific publication.

GCP guidelines state that the CSR should integrate both clinical and statistical information to provide a comprehensive overview of the trial's outcomes.

"The Clinical Study Report contains a complete and integrated presentation of clinical and statistical findings from a clinical trial."

Objectives:

* Document trial outcomes comprehensively.

* Facilitate regulatory review and scientific dissemination.

NEW QUESTION # 54

The PI may assign responsibility for IP accountability to the pharmacist provided they are:

- **A. Under the supervision of the PI.**
- B. Licensed to practice medicine.
- C. Approved by the IRB/IEC.
- D. An employee of the institution.

Answer: A

Explanation:

The Principal Investigator (PI) can delegate the responsibility for investigational product (IP) accountability to a pharmacist as long

as the pharmacist operates under the PI's supervision. This ensures that the pharmacist's actions remain compliant with the protocol and regulatory requirements.

According to GCP guidelines, the PI retains overall responsibility for IP management, even when tasks are delegated to other qualified staff members.

"The investigator may delegate IP management responsibilities to a pharmacist, provided the pharmacist works under the PI's direct supervision." Objectives:

- * Maintain accountability for investigational products.
- * Ensure proper delegation of IP responsibilities.

NEW QUESTION # 55

In a quality management system, in which category do risk reduction activities belong?

- A. Risk Control
- B. Risk Review
- C. Risk Evaluation
- D. Risk Communication

Answer: A

Explanation:

Risk reduction activities fall under Risk Control within a Quality Management System (QMS). Risk control involves implementing measures to reduce identified risks to an acceptable level, including corrective actions, preventive measures, and continuous monitoring. It aims to mitigate potential negative impacts on trial integrity and participant safety.

GCP guidelines highlight that risk control encompasses actions taken to minimize the likelihood and impact of identified risks.

"Risk control is the process of implementing measures to mitigate risks identified during the risk assessment phase." Objectives:

- * Implement effective risk management strategies.
- * Ensure proactive risk mitigation in clinical trials.

NEW QUESTION # 56

Which of the following reports should be retained in participant charts?

- A. IRB/IEC progress reports
- B. DSMB/IDMC reports
- C. Safety reports
- D. Lab reports

Answer: D

Explanation:

Lab reports contain individual participant data relevant to their health status and the study's outcomes. These reports are essential for verifying subject safety and evaluating the effects of the investigational product (IP).

Therefore, they must be retained in the participant's medical records.

According to GCP guidelines, participant charts must include laboratory data as part of the essential documents to ensure accurate and complete clinical records.

"Lab reports must be maintained as part of the participant's chart for safety monitoring and data verification." Objectives:

- * Maintain comprehensive medical records for each participant.
- * Ensure availability of clinical data for audit and review.

NEW QUESTION # 57

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