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ACRP CP FINAL EXAM LATEST 2023 REAL EXAM 150 QUESTIONS AND CORRECT ANSWERS|AGRADE

What document would an investigator reference to learn more about the previous clinical and nonclinical results of studies of the IP? - answer: **IB**

When considering participation in a study, the investigator should determine if he/she: - answer: **sees enough patients who would qualify for the study.**

When would an impartial witness be needed during the consent process for an illiterate subject? - answer: **To observe the consent process**

During a monitoring visit, what records would a CRA reference to verify a subject's compliance to the study visit schedule and assessments? - answer: **Electronic medical record**

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 cognitive ability. Which of the following individuals can administer the psychometric test to the potential subjects? - answer: **A research assistant who is certified to administer the psychometric test**

A research study, in which there is no intended clinical benefit to the subject, is being submitted to the IRB/IEC. What benefit information should be included in the ICF? - answer: **Wording indicating that there is no expected benefit should be included.**

A research subject's responsibilities for study participation should be described in the: - answer: **ICF**

New safety information has become available from the Sponsor about the IP being used in a clinical trial. The Investigator must: - answer: **submit a revised ICF to the IRB/IEC noting the new safety information.**

A medical student is approached by a faculty member for possible participation in a cricthyroidotomy simulation research study. Which of the following increases risk to the subject? - answer: **Consenting in the presence of figure of authority**

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.**

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ACRP Certified Professional Exam Sample Questions (Q10-Q15):

NEW QUESTION # 10

The sponsor must report a serious unexpected AE to the regulatory authorities within a maximum of:

- A. 7 calendar days
- B. 8 calendar days
- C. 30 calendar days
- **D. 15 calendar days**

Answer: D

Explanation:

The sponsor is required to report serious unexpected adverse events (SAEs) to the regulatory authorities within 15 calendar days from the date of awareness. This reporting period is mandated to ensure that any new safety information that may affect the risk/benefit profile of the investigational product (IP) is promptly communicated, thereby protecting participant safety.

GCP guidelines specify that serious, unexpected, and related AEs must be reported to regulatory authorities within 15 days of being known to the sponsor.

"Serious unexpected adverse reactions that may affect the safety profile of the IP must be reported within 15 calendar days to the regulatory authorities." Objectives:

- * Ensure timely reporting of safety information.
- * Protect the safety of trial participants.

NEW QUESTION # 11

Which of the following should be reviewed and evaluated by qualified experts to assess implications for the safety of the trial subjects?

- A. Project feasibility considerations
- B. PI roles and responsibilities
- **C. Emerging animal toxicological and clinical data**
- D. Sample collection storage, disposal, and shipment requirements

Answer: C

Explanation:

Qualified experts should evaluate emerging animal toxicological and clinical data to assess potential safety implications for trial subjects. These data are critical in identifying potential risks, adverse effects, or safety concerns before exposing human subjects to the investigational product. Early detection of safety issues through expert evaluation helps protect participant well-being. GCP guidelines stress the importance of expert assessment of preclinical and clinical data to identify risks and ensure participant safety.

"Emerging toxicological and clinical data should be carefully reviewed by qualified experts to identify safety concerns before clinical use." Objectives:

- * Ensure participant safety through expert data analysis.
- * Identify potential safety risks early in the trial process.

NEW QUESTION # 12

Who is responsible for outlining written procedures in a study to assure that changes or corrections in CRFs are documented, are necessary, and are endorsed by the investigator?

- A. CRO
- **B. Sponsor**
- C. Data Manager
- D. CRA

Answer: B

Explanation:

The sponsor is responsible for establishing written procedures to ensure that all changes or corrections in Case Report Forms (CRFs) are properly documented and justified. These procedures must include who is authorized to make changes, how corrections are documented, and how they are endorsed by the investigator.

This practice ensures data accuracy and traceability.

GCP guidelines indicate that sponsors must establish and maintain procedures for data handling and documentation to ensure accuracy and reliability.

"The sponsor should develop written procedures to ensure that CRF changes are justified, documented, and endorsed by the investigator." Objectives:

- * Maintain data accuracy and consistency.
- * Ensure transparent documentation practices.

NEW QUESTION # 13

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

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

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 # 14

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

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

Answer: B

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 # 15

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