ACRP ACRP-CP PDF Questions–Ideal Material for Quick Preparation

ACRP CP PRACTICE QUESTIONS WITH ANSWERS 2023

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.

CRO recently switched from paper CRF to an EDC system. The EDC system must conform to the established requirements for: - Answer Validation, accuracy, reliability, completeness

Part of a sponsor's responsibility pertaining to electronic trial data handling is to - Answer maintain an audit trail, data trail, and edit trail.

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

What document would an investigator reference to learn more about the previous clinical and nonclinical results of studies of the IP? - Answer Investigators brochure

During a multi site clinical study, whose responsibility is it to report subject recruitment rate? - Answer The CRA

An unconscious adult subject was enrolled in a study after obtaining consent from an LAR, and protocol therapy was initiated. The subject showed significant improvement in his clinical condition, and regained consciousness. The Investigator should inform the subject about the study and - Answer Obtain consent from the subject for the study

A site is in the start up phase of an industry sponsored phase 3 trial, and has received IRB approval. The site can begin enrolling subjects after... - Answer A signed clinical trial agreement between the site and sponsor is in place

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. What benefit informatiom should be included in the ICF? - Answer Wording indicating that there is no expected benefit should be included

A CRA notices during an onsite visit that the date on IRB approval letter for a protocol is prior to the effective date indicated on the cover page of the protocol and the signatures of the investigator and sponsor. What should the CRA do FIRST? - Answer Confirm dates of initial receipt of the sponsor protocol and the IRB submission dates.

In a multi arm, randomized clinical trial, one arm of the protocol was terminated due to an increased risk of cancer in subjects. Who is responsible for providing a written report to the IRB? - Answer PI

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ACRP Certified Professional Exam Sample Questions (Q66-Q71):

NEW QUESTION # 66
Upon receipt of temperature-controlled IP, the study staff noticed the IP incurred a temperature excursion during transport. What should the staff do NEXT?

- A. Register IP in IWRS, quarantine and notify sponsor of the excursion.
- B. Dispose of IP and request replacement from sponsor.
- C. Quarantine IP without registering in IWRS and request replacement from sponsor.
- D. Register IP in IWRS and continue with subject allocation.

Answer: A

Explanation:
If a temperature-controlled IP has experienced a temperature excursion during transport, the appropriate action is to register the IP in the Interactive Web Response System (IWRS), quarantine it to prevent use, and immediately notify the sponsor. This procedure ensures that the IP is not used until the sponsor evaluates its stability and suitability.
GCP guidelines state that any IP affected by a temperature excursion should be quarantined and reported to the sponsor for evaluation.
"Upon identification of a temperature excursion, the IP must be quarantined and reported to the sponsor to determine its usability."
Objectives:
* Maintain IP integrity and compliance with storage conditions.
* Follow protocol for managing temperature excursions.

NEW QUESTION # 67
The objective of a randomized clinical trial is to look at whether an IP is effective in preventing recurrence of a disease. What would be a possible primary endpoint of the trial?

- A. Use of concomitant medications to treat the symptoms
- B. Impact of an approved vaccine against the disease
- C. Time to occurrence of symptoms of the disease
- D. Occurrence of known side effects of the IP

Answer: C

Explanation:
In a clinical trial aimed at assessing whether an IP prevents disease recurrence, the primary endpoint would typically be the "time to occurrence of symptoms" indicating a relapse or recurrence. This endpoint directly measures the IP's effectiveness in prolonging the symptom-free period.
This answer follows the GCP guideline, which states that primary endpoints should directly reflect the trial's objectives, particularly when evaluating recurrence prevention.
"In trials evaluating recurrence prevention, the primary endpoint should measure the time until recurrence of the target symptoms or condition." Objectives:
* Assess the efficacy of IP in preventing disease recurrence.
* Accurately measure the time to recurrence as a primary endpoint.

NEW QUESTION # 68
A quality assurance audit of the EDC system SOP revealed a deficiency. Which of the following is the MOST likely reason?

- A. The list of comparable technology solutions was not included.
- B. The number of unique eCRF templates was not specified.
- C. The frequency of data backup was not defined.
- D. The number of users with access was not defined.

Answer: C

Explanation:
The frequency of data backup is a critical element of an Electronic Data Capture (EDC) system's Standard Operating Procedure (SOP). Ensuring regular and systematic data backup is essential for protecting trial data against loss or corruption. Failure to specify backup frequency indicates a gap in data security management.
GCP guidelines stress that data protection, including regular backups, is essential to maintaining data integrity in clinical trials.
"EDC system SOPs must include clear guidelines on data backup frequency to safeguard the integrity and availability of study data."
Objectives:
* Ensure data security through regular backups.
* Maintain data integrity in clinical research.

NEW QUESTION # 69
Which of the following is a conflict of interest for a PI conducting a study?

- A. A PI that votes on the IRB/IEC approval of the protocol
- B. A PI who is a key opinion leader, writes the protocol
- C. A PI that presents at an investigator meeting
- D. A PI who receives payment for the study

Answer: A

Explanation:
A Principal Investigator (PI) who is involved in voting on the IRB/IEC approval of their own protocol is considered to have a conflict of interest. The IRB/IEC must be independent and impartial when reviewing research proposals. Allowing the PI to vote on their own study compromises the ethical review process. To maintain unbiased decision-making, PIs must recuse themselves from such votes.
GCP guidelines emphasize the importance of avoiding conflicts of interest in the IRB/IEC decision-making process to maintain objectivity and ethical standards.
"A PI should not participate in voting or decision-making processes regarding the approval of their own study to avoid conflicts of interest." Objectives:
* Maintain impartiality in ethical review.
* Prevent conflicts of interest during IRB/IEC processes.

NEW QUESTION # 70
The sponsor must report a serious unexpected AE to the regulatory authorities within a maximum of:

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

Answer: C

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 # 71
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