ACRP-CP시험대비최신버전문제인증시험자료

ACRP CP Practice Questions and Answers (2023 – 2024) With Complete Solution

What would be the first priority for an investigator when a subject wishes to withdraw prematurely from the trial? - 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: - Validation, accuracy, reliability, completeness

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

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

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

During a multi site clinical study, whose responsibility is it to report subject recruitment rate? - 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 - 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... - 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? - 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? - 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? - Confirm dates of initial receipt of the sponsor protocol and the IRB submission dates.

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최신 ACRP Certified Professional ACRP-CP 무료샘플문제 (Q82-Q87):

질문 # 82
An interim analysis is conducted during a clinical trial. To review the results, the sponsor assigns:

- A. Investigators participating in the trial.
- B. Independent qualified individuals.
- C. Executive board members.
- D. Regulatory authority expert advisors.

정답：B

설명：
Interim analysis should be reviewed by independent qualified individuals, such as members of a Data Safety Monitoring Board (DSMB) or Independent Data Monitoring Committee (IDMC). This ensures that the analysis is unbiased and that decisions regarding continuation, modification, or termination of the trial are made objectively.
GCP guidelines emphasize that interim data should be reviewed by an independent committee to prevent bias and ensure participant safety.
"Interim analyses should be conducted by independent experts to maintain objectivity and safeguard trial integrity." Objectives:
* Maintain impartiality during interim analysis.
* Ensure unbiased decision-making regarding trial continuation.

질문 # 83
The PI should ensure that source data is:

- A. Accurately reflected in the eCRFs.
- B. Kept on site for a minimum of 2 years.
- C. Printed directly from the EMR.
- D. On worksheets that are provided by the sponsor.

정답：A

설명：
The PI is responsible for ensuring that the source data is accurately recorded in the electronic Case Report Forms (eCRFs). This accurate transposition of data is critical to maintaining data integrity and ensuring that the data collected at the site is consistent with the reported clinical outcomes.
GCP guidelines specify that source data should be accurate, legible, and directly reflected in the CRFs to maintain consistency and reliability.
"The PI must ensure that the source data are accurately and completely recorded in the eCRFs to maintain data integrity."
Objectives:
* Ensure accurate data transposition from source to CRF.
* Maintain high standards of data quality and reliability.

질문 # 84
While reviewing reports of data completion, the sponsor notices low retention rates at many participating sites. What is an appropriate FIRST action for the sponsor to take?

- A. Submit revised ICFs to the IRB/IEC with increased compensation for participants.
- B. Require participants to provide documented reason for withdrawal.
- C. Interview participants who have dropped out.
- D. Meet with the site staff to understand their workflows and to review retention strategies.

정답：D

설명：
Meeting with site staff to understand workflows and retention strategies is the most practical first step. By engaging with the team, the sponsor can identify potential issues affecting retention, such as site-related factors, participant burden, or protocol complexities. Addressing these issues collaboratively can improve retention without needing major protocol changes.
GCP guidelines recommend assessing and understanding site-specific challenges before making procedural changes or protocol amendments.
"Engaging with site staff to discuss retention issues helps identify root causes and develop practical solutions." Objectives:

* Improve participant retention through collaboration.
* Identify and address site-specific challenges.

질문 # 85
A sponsor wants to transfer duties to a CRO. Which of the following statements is the MOST correct?

- A. Regulatory authorities must be notified promptly of the transfer of any duties to a CRO.
- B. All duties transferred to a CRO should be specified in writing.
- C. The IRB/IEC must approve the transfer of duties to a CRO.
- D. Any trial-related duties can be documented as transferred by verbal agreement.

정답：B

설명：
When a sponsor transfers specific tasks to a Contract Research Organization (CRO), it must be documented in writing. This formal documentation clearly delineates responsibilities and ensures that both parties are aware of their roles and obligations. Verbal agreements are not sufficient forregulatory compliance.
ICH E6(R2) GCP guidelines mandate that all delegated tasks must be documented formally to ensure clarity and compliance.
"The sponsor should document in writing any responsibilities transferred to a CRO to ensure clear delineation of roles." Objectives:
* Maintain clear documentation of delegated tasks.
* Ensure compliance with regulatory standards.

질문 # 86
Who is responsible for securing agreement from all involved parties to ensure direct access of all trial-related source documents?

- A. Sponsor
- B. Investigator
- C. CRO
- D. CRC

정답：A

설명：
The sponsor is responsible for ensuring that agreements are in place with all involved parties (including investigators and institutions) to grant direct access to trial-related source documents. This is crucial for monitoring, auditing, and inspection purposes, ensuring transparency and compliance with regulatory requirements.
According to GCP guidelines, the sponsor must establish agreements to secure direct access to trial data for verification and compliance checks.
"The sponsor should ensure that agreements are in place to permit direct access to source data and documents for monitoring and inspection." Objectives:
* Maintain compliance with regulatory requirements.
* Facilitate data verification and quality assurance.

질문 # 87
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