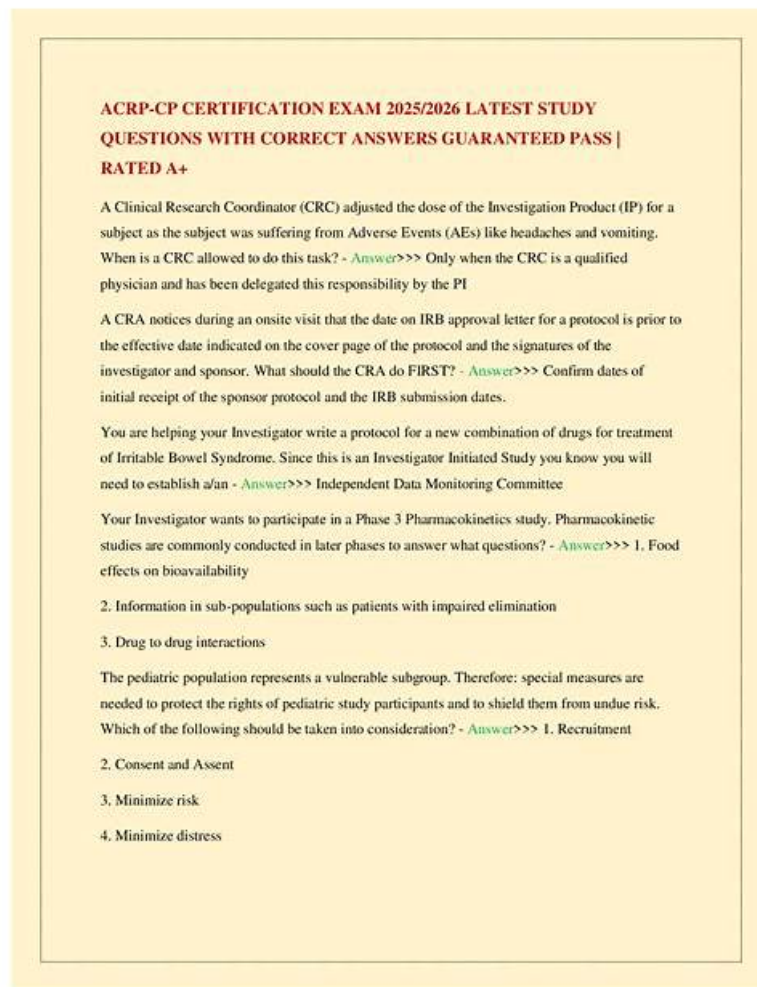


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ACRP Certified Professional Exam Sample Questions (Q74-Q79):

NEW QUESTION # 74

Confidentiality and privacy rules for protection of human subjects at research sites are determined by the:

- A. Sponsor
- B. Applicable site SOPs
- C. Applicable regulatory authorities
- D. PI

Answer: C

Explanation:

The confidentiality and privacy rules protecting human subjects in clinical research are established by applicable regulatory authorities, such as the FDA or EMA, and must be followed by all research sites. These regulations ensure that participants' personal data are handled securely and ethically.

GCP guidelines mandate compliance with local, national, and international regulations regarding data confidentiality and privacy.

"Confidentiality and privacy protections are determined by applicable regulatory authorities and must be adhered to by all study sites." Objectives:

- * Protect participant privacy.
- * Ensure compliance with data protection regulations.

NEW QUESTION # 75

In order to conduct open-label, parallel group clinical trials according to sound scientific principles, which of the following design elements should be included?

- A. Privacy controls
- B. Placebo-controlled
- C. Blinding
- D. Randomization

Answer: D

Explanation:

Randomization is a key element in open-label, parallel group clinical trials to reduce selection bias and ensure that participant allocation is not influenced by investigators. Despite the absence of blinding in open-label studies, randomization maintains the validity and reliability of the results by evenly distributing confounding factors between groups.

GCP guidelines recommend randomization as a core element in clinical trial design to ensure unbiased allocation of participants.

"Randomization in parallel group trials helps minimize selection bias and ensures the comparability of intervention groups."

Objectives:

- * Maintain scientific rigor through randomization.
- * Minimize selection bias in clinical studies.

NEW QUESTION # 76

Who is responsible for defining, establishing, and allocating all trial-related duties and functions prior to initiating a trial?

- A. Sponsor
- B. Investigator
- C. IRB/IEC
- D. CRO

Answer: A

Explanation:

The sponsor is responsible for defining, establishing, and allocating all trial-related duties and functions before the trial begins. This includes outlining roles and responsibilities in collaboration with investigators, CROs, and other stakeholders. Proper delegation ensures the trial is conducted according to protocol and regulatory requirements.

This answer is verified based on GCP guidelines, which clearly state that sponsors are responsible for the organization and management of trial-related tasks.

"The sponsor is responsible for allocating duties and functions related to the conduct of the trial, ensuring compliance with regulatory and ethical standards." Objectives:

- * Clarify the sponsor's role in clinical trial management
- * Define responsibilities in trial planning

NEW QUESTION # 77

After enrolling and treating a few subjects on an investigator-initiated trial, the PI would like to include a subject diary for each trial subject to capture their activities and experiences on the trial regimen. After the PI has generated a diary, what should the PI do next?

- A. Submit the diary to the sponsor for approval.
- **B. Submit the diary to the IRB/IEC for approval.**
- C. No approval is necessary: give the diary to each subject.
- D. Submit the diary to the regulatory authority for approval.

Answer: B

Explanation:

Any new data collection tool introduced during a clinical trial, including subject diaries, must be reviewed and approved by the IRB/IEC before implementation. This ensures that the new tool is ethically appropriate, respects subject privacy, and aligns with the approved protocol.

This answer aligns with ICH E6(R2) GCP guidelines, which mandate IRB/IEC approval for any new or modified subject-related documents introduced during a trial.

"All changes in study documents, including subject diaries, must be submitted for IRB/IEC review to ensure compliance with ethical standards." Objectives:

- * Maintain compliance with IRB/IEC requirements.
- * Ensure ethical handling of subject data.

NEW QUESTION # 78

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

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

Answer: B

Explanation:

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.

NEW QUESTION # 79

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