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ACRP Certified Professional Exam Sample Questions (Q27-Q32):

NEW QUESTION # 27

Who should vote during the IRB/IEC review and discussion process?

- A. All IRB/IEC members and non-member experts
- **B. All members who were involved in the review and discussion**
- C. All IRB/IEC members
- D. All members who were involved in the review and discussion and non-member experts

Answer: B

Explanation:

During the IRB/IEC review process, only members who actively participated in the review and discussion are eligible to vote. This ensures that votes are cast by those who are adequately informed about the study and can make an educated decision. Non-member experts may participate in discussions but do not have voting rights.

GCP guidelines state that voting rights in IRB/IEC meetings are limited to members who have thoroughly reviewed and discussed the study, maintaining unbiased and informed decision-making.

"Only IRB/IEC members who were involved in the review and discussion should participate in the voting process." Objectives:

- * Ensure informed voting in ethical review processes.
- * Maintain integrity and objectivity in IRB/IEC decisions.

NEW QUESTION # 28

The IRB/IEC has decided to not approve a clinical trial. Who must they notify in writing?

- A. Sponsor
- B. Regulatory Agency
- **C. PI**
- D. CRC

Answer: C

Explanation:

When the IRB/IEC decides not to approve a clinical trial, they must notify the Principal Investigator (PI) in writing. This communication ensures that the PI is formally informed of the decision and can take appropriate actions, such as revising the protocol or addressing the reasons for disapproval.

According to GCP guidelines, the IRB/IEC must communicate any decision regarding the approval status of a study directly to the PI, as the PI is responsible for the conduct of the trial.

"The IRB/IEC should promptly notify the investigator in writing of its decision to approve or disapprove the proposed research activity." Objectives:

- * Maintain clear communication between the IRB/IEC and the investigator.
- * Ensure timely notification of decisions affecting the study.

NEW QUESTION # 29

SAEs must be reported immediately by the site to the:

- A. IRB/IEC.
- B. DSMB/IDMC.
- C. Regulatory agency.
- **D. Sponsor.**

Answer: D

Explanation:

Serious Adverse Events (SAEs) must be reported immediately to the sponsor. The sponsor then assesses the severity, causality, and potential impact on the study and decides whether further reporting to regulatory authorities and IRB/IEC is required. Immediate reporting ensures that appropriate actions are taken to safeguard participant safety.

GCP guidelines specify that the site must notify the sponsor immediately about any SAE to ensure timely safety assessment and reporting.

"Sites must report all serious adverse events immediately to the sponsor, who will then determine the appropriate regulatory and ethical reporting requirements." Objectives:

- * Ensure rapid reporting of serious adverse events.
- * Maintain safety monitoring during the trial.

NEW QUESTION # 30

Who takes responsibility for initiating a clinical trial?

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

Answer: A

Explanation:

The sponsor is responsible for initiating a clinical trial. This involves developing the protocol, securing funding, selecting study sites, and obtaining regulatory approvals. The sponsor also oversees the conduct of the trial to ensure compliance with GCP and regulatory requirements.

According to GCP guidelines, the sponsor is the entity that initiates, manages, and finances the clinical investigation.

"The sponsor is responsible for initiating, managing, and financing the clinical trial, including protocol development and site selection."

Objectives:

- * Understand the sponsor's role in trial initiation.
- * Ensure compliance from the outset of the study.

NEW QUESTION # 31

Access to study documentation for auditors and inspectors during an audit or inspection at a clinical trial site is the responsibility of the:

- A. Sponsor
- B. CRA
- C. PI
- D. CRC

Answer: C

Explanation:

The Principal Investigator (PI) is responsible for providing access to study documentation during an audit or inspection. This includes regulatory files, participant records, and study logs. The PI ensures that auditors and inspectors have appropriate access while maintaining the confidentiality of subject data.

GCP guidelines clearly assign the responsibility for maintaining and granting access to trial documentation to the PI at the study site.

"The PI is responsible for ensuring that study-related documents are available for review during audits or inspections." Objectives:

- * Maintain transparency during inspections.
- * Ensure compliance with documentation requirements.

NEW QUESTION # 32

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