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ACRP Certified Professional Exam Sample Questions (Q22-Q27):

NEW QUESTION # 22

Which of the following documents is maintained by a PI to ensure compliance with sponsor requirements?

- A. A monitoring report that identifies deviation from the approved protocol.
- **B. Training records of site personnel on study protocol, and their study-related duties and functions.**
- C. A monitoring plan that is tailored to the specific human subject protection and data integrity risks of the trial.
- D. Regulatory submission of protocol and accompanying documents to relevant regulatory authority.

Answer: B

NEW QUESTION # 23

A monitor identifies multiple deviations from a protocol-defined timeline for study procedures. The monitor is unable to identify proof of PI review and assessment of the deviations. The monitor discusses the deviations with the PI, who initiates a CAPA. What is the purpose of this CAPA?

- **A. To establish a procedure for PI oversight of protocol deviations**
- B. To determine if the deviations invalidate the data
- C. To determine if a protocol amendment is needed
- D. To escalate corrective actions to the regulatory authority

Answer: A

Explanation:

A Corrective and Preventive Action (CAPA) plan is implemented to address deviations and prevent them from recurring. In this context, the purpose of the CAPA is to establish a procedure for the Principal Investigator (PI) to ensure proper oversight of protocol deviations. This ensures that all future deviations are appropriately managed, reviewed, and documented according to GCP standards.

The answer is verified from GCP guidelines which emphasize that CAPA should focus on identifying root causes and establishing processes to prevent future deviations.

"A CAPA plan must address the root cause and implement systematic actions to prevent the recurrence of protocol deviations."

Objectives:

- * Ensuring PI oversight in protocol adherence
- * Maintaining data integrity through systematic corrective actions

NEW QUESTION # 24

While consenting a potential subject, a coordinator discovered the subject could not read. Under what conditions can this potential subject be enrolled?

- A. Have the Principal Investigator consent the person.
- B. There are no circumstances under which this person can be enrolled.
- C. Locate a translator and have them work with the person.
- **D. Get an impartial witness involved in consenting this person.**

Answer: D

Explanation:

When a participant cannot read, an impartial witness must be present during the consent process. The witness ensures that the information is accurately presented and that the subject's consent is truly informed. The witness must sign the consent form to attest that the subject understands the information.

GCP guidelines require the use of an impartial witness during the informed consent process for individuals who are illiterate or visually impaired.

"Informed consent must involve an impartial witness when the subject cannot read, ensuring the consent process is conducted ethically." Objectives:

- * Maintain ethical standards during consent.
- * Protect the rights of participants with literacy challenges.

NEW QUESTION # 25

A new device trial is being considered. Before committing to participate in the trial, what is the MOST important item the PI needs to evaluate?

- A. Location of stored trial records
- B. Length of time to receive the approved trial device
- C. Availability of qualified staff to conduct the trial
- D. Information to be included in the advertising flyer

Answer: C

Explanation:

The availability of qualified staff to conduct the trial is essential for maintaining compliance with protocol requirements and ensuring patient safety. Without adequately trained and available staff, the trial's integrity and data quality are compromised.

This answer is based on GCP guidelines emphasizing the importance of having trained and qualified personnel before initiating a trial. "The PI must ensure that sufficient qualified staff is available to conduct the trial as per the protocol and regulatory requirements."

Objectives:

- * Assessing resource availability
- * Ensuring readiness to initiate a clinical trial

NEW QUESTION # 26

An investigator in a multicenter trial reports multiple occurrences of an SAE to the sponsor. Who is responsible for reporting the SAEs to the remaining sites' IRB/IECs?

- A. Study sponsor
- B. Investigator at each site
- C. Original reporting investigator
- D. Regulatory authority

Answer: A

Explanation:

The study sponsor is responsible for disseminating information about SAEs to all participating sites. This ensures consistent and timely communication of safety concerns, allowing each site to take appropriate actions in line with local regulations and IRB/IEC requirements.

The answer aligns with ICH E6(R2) GCP guidelines which mandate the sponsor to communicate safety information to all investigators and sites involved in a multicenter trial.

"The sponsor must inform all investigators of safety information that could affect the conduct of the trial or the safety of subjects."

Objectives:

- * Maintain consistent safety reporting across all trial sites.
- * Ensure regulatory compliance in multicenter trials.

NEW QUESTION # 27

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