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

NEW QUESTION # 66

Who is responsible to ensure training for key staff members unable to attend the site initiation visit?

- A. Investigator
- B. Coordinator
- C. Monitor
- D. Sponsor

Answer: A

Explanation:

The Principal Investigator (PI) is responsible for ensuring that all site staff involved in the study are adequately trained, even if they were unable to attend the Site Initiation Visit (SIV). This responsibility includes organizing training sessions or providing relevant training materials to maintain consistency and compliance with study protocols.

According to GCP guidelines, the PI must ensure that all staff members involved in the trial are adequately informed and trained on their specific responsibilities.

"The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions." Objectives:

- * Maintain consistent training for all clinical staff.
- * Ensure compliance with study procedures.

NEW QUESTION # 67

During a monitoring visit, a CRA notices that a piece of equipment required for the study needs to be serviced. Who is responsible for addressing this problem?

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

Answer: C

Explanation:

The Principal Investigator (PI) is responsible for ensuring that all equipment used in the clinical trial is properly maintained and serviced. If a monitor (CRA) identifies equipment that needs servicing, the PI must take immediate action to ensure the equipment is in working order to maintain the quality and integrity of the study data.

GCP guidelines emphasize the PI's responsibility to ensure that all equipment used in the study is functional, properly calibrated, and serviced as needed.

"The PI is responsible for maintaining the functionality and calibration of study-related equipment to ensure accurate data collection."

Objectives:

Maintain equipment functionality to ensure data accuracy.

Ensure proper maintenance as part of site management.

NEW QUESTION # 68

A site is starting up a Phase III trial. They have received IRB/IEC approval and have scheduled the SIV. The site cannot begin enrolling subjects until:

- A. The DSMB meets and the first DSMB meeting report has been issued.
- B. The CRA has performed source document review and verification at the site.
- C. The site receives approval from the medical monitor to begin enrolling.
- D. A signed clinical trial agreement between the site and sponsor is in place.

Answer: D

Explanation:

Before a clinical trial site can begin enrolling participants, there must be a signed clinical trial agreement (CTA) between the site and the sponsor. This agreement outlines the responsibilities, financial arrangements, and expectations between both parties, ensuring that the trial is conducted in compliance with regulatory and ethical standards.

GCP guidelines require that a formal agreement be in place before trial initiation to protect the rights and obligations of both the sponsor and the site.

"Before subject enrollment can commence, the sponsor and site must finalize a clinical trial agreement, establishing legal and ethical commitments." Objectives:

- * Ensure proper contractual arrangements before trial initiation.
- * Protect legal rights and obligations of involved parties.

NEW QUESTION # 69

Who determines what criteria and procedures should be followed if a subject discontinues/withdraws their consent?

- A. CRO
- B. Sponsor
- C. PI
- D. Subject

Answer: B

Explanation:

The sponsor is responsible for defining the criteria and procedures for subject withdrawal or discontinuation of consent. This includes specifying how data already collected will be handled and whether any follow-up is required. The procedures must be clearly outlined in the study protocol and communicated to the research team.

This answer follows GCP guidelines, which state that the sponsor must ensure that procedures for subject withdrawal are clearly defined and documented.

"The sponsor is responsible for defining procedures to be followed if a subject discontinues participation or withdraws consent, including handling of data collected prior to withdrawal." Objectives:

- * Ensure transparent procedures for participant withdrawal.
- * Maintain data integrity while respecting participant autonomy.

NEW QUESTION # 70

Which of the following statements accurately describes the responsibilities of stakeholders involved in the conduct of a clinical study?

- A. The IRB/IEC is responsible for obtaining consent from all subjects in the clinical study.
- B. The sponsor is responsible for overseeing any delegated activities to a CRO and ensuring that the delegation of these activities is documented.
- C. The regulatory authority is responsible for assessing and approving the clinical study protocol and accompanying CRF prior to implementation.
- D. The CRC is responsible for identifying the relationship of an SAE to the IP.

Answer: B

Explanation:

The sponsor holds the responsibility for overseeing any activities delegated to a Contract Research Organization (CRO). This includes ensuring that all delegated tasks are clearly documented and that the CRO performs them according to regulatory standards and the study protocol.

GCP guidelines state that while the sponsor may delegate tasks to a CRO, the ultimate responsibility for the trial's conduct remains with the sponsor.

"The sponsor retains responsibility for overseeing any delegated tasks to the CRO and must ensure that these responsibilities are appropriately documented." Objectives:

- * Clarify delegation of duties in clinical trials.
- * Maintain sponsor oversight for regulatory compliance.

NEW QUESTION # 71

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