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## Latest ACRP-CP Exam Questions - ACRP-CP Latest Test Dumps

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## ACRP Certified Professional Exam Sample Questions (Q53-Q58):

### NEW QUESTION # 53

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

**Answer: C**

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 # 54**

Which of the following should be reviewed and evaluated by qualified experts to assess implications for the safety of the trial subjects?

- A. Sample collection storage, disposal, and shipment requirements
- **B. Emerging animal toxicological and clinical data**
- C. PI roles and responsibilities
- D. Project feasibility considerations

**Answer: B**

Explanation:

Qualified experts should evaluate emerging animal toxicological and clinical data to assess potential safety implications for trial subjects. These data are critical in identifying potential risks, adverse effects, or safety concerns before exposing human subjects to the investigational product. Early detection of safety issues through expert evaluation helps protect participant well-being.

GCP guidelines stress the importance of expert assessment of preclinical and clinical data to identify risks and ensure participant safety.

"Emerging toxicological and clinical data should be carefully reviewed by qualified experts to identify safety concerns before clinical use." Objectives:

- \* Ensure participant safety through expert data analysis.
- \* Identify potential safety risks early in the trial process.

#### **NEW QUESTION # 55**

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

- A. Investigator
- **B. Sponsor**
- C. CRC
- 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 # 56**

Per protocol, participants are scheduled to receive IP, which is calculated based on the participant's current weight. Unknown to the pharmacist, a participant recently lost 15 pounds and was overdosed as a result. What is the FIRST action the CRC must take to ensure the participant's safety?

- A. Notify the sponsor.
- B. Call the participant to return for an unscheduled visit.
- **C. Notify the PI.**
- D. Report a protocol deviation to the IRB/IEC.

**Answer: C**

Explanation:

The CRC's first responsibility is to immediately inform the Principal Investigator (PI), who is responsible for the participant's medical care. The PI will assess the situation, determine the potential risk, and initiate appropriate clinical actions to ensure the participant's safety. This may include medical evaluation or adjusting the dosing regimen.

According to GCP guidelines, any issue that may affect participant safety should be promptly communicated to the PI to ensure appropriate medical management.

"The investigator must be informed immediately of any events that could compromise participant safety, allowing for prompt clinical decision-making." Objectives:

- \* Ensure rapid response to dosing errors.
- \* Maintain participant safety as a priority.

#### **NEW QUESTION # 57**

Prior to initiation of a clinical trial, review by an IRB/IEC is required for which of the following documents?

- A. Protocol, site coordinator CVs, and clinical trial agreement
- **B. Protocol, IB, and information about payments and compensation available to subjects**
- C. Protocol, informed consent, and clinical trial agreement
- D. IB, site coordinator CVs, and information about payments and compensation available to subjects

**Answer: B**

Explanation:

Before a clinical trial can begin, the IRB/IEC must review the protocol, Investigator's Brochure (IB), and any information related to payments and compensation. This review ensures that the study is ethically sound, scientifically valid, and that participants are informed about any financial considerations.

GCP guidelines specify that essential documents, including the protocol, IB, and compensation details, must be reviewed by the IRB/IEC to maintain ethical oversight.

"The IRB/IEC must evaluate the protocol, IB, and any financial disclosures to ensure ethical compliance and participant protection."

Objectives:

- \* Guarantee ethical oversight in clinical trial conduct.
- \* Protect participants through informed consent and transparency.

#### **NEW QUESTION # 58**

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