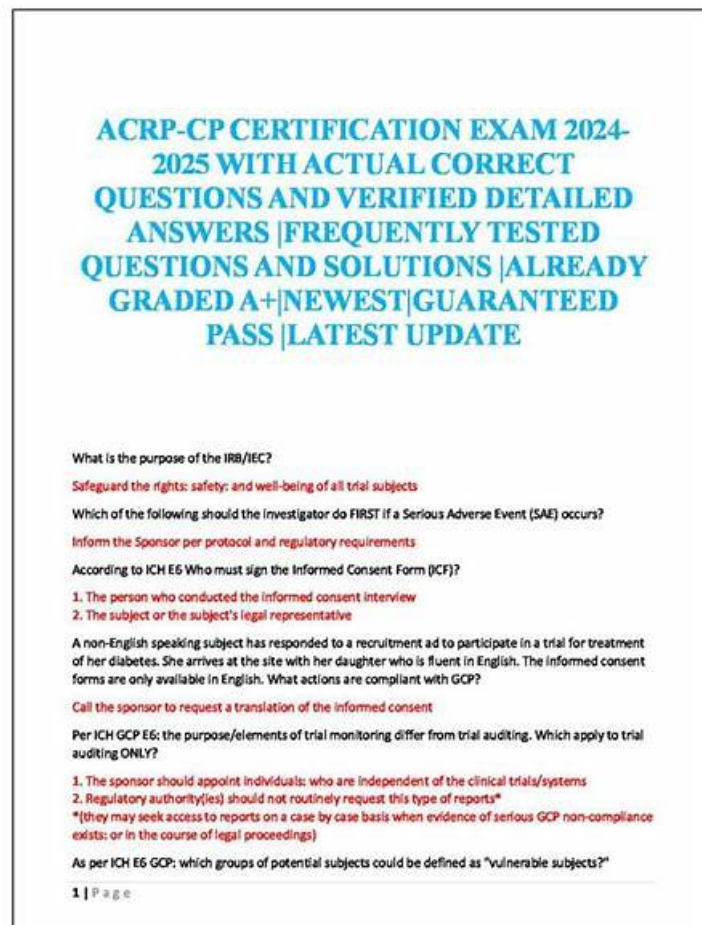


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ACRP Certified Professional Exam Sample Questions (Q123-Q128):

NEW QUESTION # 123

What is a systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial-related activities were conducted and the data were recorded, analyzed, and accurately reported according to the protocol, sponsors, SOPs, GCP, and the applicable regulatory requirements?

- A. Routine monitoring
- B. Inspection
- C. Site qualification
- **D. Audit**

Answer: D

Explanation:

An audit is a systematic and independent examination of trial-related activities and documents. Its purpose is to determine whether the study was conducted in compliance with the protocol, GCP, and regulatory requirements. Audits are usually performed by the sponsor or an independent auditor and focus on evaluating data integrity and trial conduct.

GCP guidelines define an audit as a thorough examination to ensure adherence to protocol and regulatory requirements.

"An audit is a systematic and independent examination of trial-related activities to verify compliance with the protocol and regulatory standards." Objectives:

Ensure compliance and data integrity.

Identify any gaps in trial conduct.

NEW QUESTION # 124

Which strategy is used to safeguard subject privacy?

- A. Store source documentation in the CRC's office.
- B. Email updated enrollment logs to the CRA.
- C. Utilize subject initials on correspondence.
- **D. Conduct subject-related conversations in controlled environments.**

Answer: D

Explanation:

Conducting subject-related conversations in controlled environments ensures that personal and sensitive information is not overheard or disclosed to unauthorized individuals. This practice upholds patient confidentiality as required by GCP and data protection regulations.

The answer follows GCP guidelines for protecting the privacy and confidentiality of clinical trial participants.

"Conversations regarding study subjects should be held in secure and controlled environments to protect personal data." Objectives:

* Ensuring confidentiality in clinical trial settings.

* Protecting patient privacy according to ethical standards.

NEW QUESTION # 125

All of the following are examples of what monitors review EXCEPT:

- A. Regulatory binder which includes copies of current certifications for all laboratories.
- B. The signed ICF retained in the participant's study file.
- C. Documentation in the participant's medical record of study drug administration.
- **D. Potential patient medical records for eligibility prior to the informed consent process.**

Answer: D

Explanation:

Monitors are responsible for reviewing documents that pertain to study conduct and data integrity, including regulatory binders, informed consent forms (ICFs), and documentation of study drug administration.

However, reviewing potential patient medical records for eligibility prior to the informed consent process is not part of a monitor's responsibilities, as this would violate patient confidentiality and GCP standards.

According to GCP guidelines, monitors should ensure compliance with the protocol and data integrity but should not access non-

consented patient records.

"Monitors should verify that only enrolled and consented subjects' data are reviewed, ensuring compliance with privacy regulations."

Objectives:

- * Understand the scope of monitoring responsibilities.
- * Protect patient confidentiality during the monitoring process.

NEW QUESTION # 126

A study is using an EDC system. After the data is entered into EDC, who is the next to review and conduct SDV of this data?

- A. Sponsor
- **B. Monitor**
- C. Data Manager
- D. QA Department

Answer: B

Explanation:

After data entry into the Electronic Data Capture (EDC) system, the monitor (typically a Clinical Research Associate - CRA) conducts Source Data Verification (SDV). The monitor compares the data entered in the EDC system with the source documents to ensure accuracy, completeness, and consistency. This step is essential for maintaining data integrity and compliance with GCP standards.

GCP guidelines require that monitors verify data accuracy through SDV as part of routine monitoring responsibilities.

"The monitor is responsible for performing Source Data Verification (SDV) to ensure that the data recorded in the EDC system matches the source documents." Objectives:

- * Verify data accuracy in clinical trials.
- * Ensure compliance with data management protocols.

NEW QUESTION # 127

Which entity has ultimate responsibility over the conduct of the multi-center clinical trial?

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

Answer: B

Explanation:

In a multi-center clinical trial, the Sponsor-Investigator holds ultimate responsibility for the overall conduct of the study. This includes ensuring compliance with the protocol, maintaining data integrity, and overseeing all participating sites. The Sponsor-Investigator must ensure that each site follows the same procedures and standards to maintain consistency across the trial.

According to GCP guidelines, the Sponsor-Investigator must take responsibility for all aspects of a multi-center trial, including site coordination and data management.

"The Sponsor-Investigator assumes ultimate responsibility for the conduct of a multi-center clinical trial, ensuring protocol compliance and data consistency." Objectives:

- * Maintain accountability across multi-center sites.
- * Ensure uniformity in trial conduct.

NEW QUESTION # 128

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