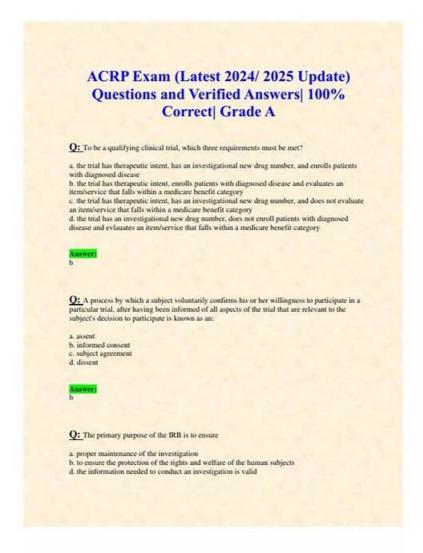
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### ACRP Certified Professional Exam Sample Questions (Q52-Q57):

#### **NEW OUESTION #52**

An audit was recently completed and identified non-compliance that could potentially affect the reliability of study results. Who should perform a root cause analysis and implement appropriate corrective and preventive actions?

- A. IRB/IEC
- B. DSMB/IDMC
- C. PI
- D. Sponsor

#### Answer: C

#### Explanation:

The Principal Investigator (PI) is responsible for conducting a root cause analysis when non-compliance is identified at the site. The PI must identify the reasons for non-compliance and develop a Corrective and Preventive Action (CAPA) plan to address and prevent future occurrences.

This answer aligns with GCP principles that designate the PI as responsible for site-level compliance and corrective actions.

"The PI must take responsibility for investigating the cause of non-compliance and developing a CAPA plan to mitigate recurrence."

Objectives:

- \* Maintaining compliance and data integrity
- \* Addressing non-compliance proactively

#### **NEW QUESTION #53**

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

#### Answer: C

#### 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 #54**

The process of ensuring and documenting that an electronic data processing system conforms to the sponsor's established requirements for completeness, accuracy, reliability, and consistent intended performance is called:

- A. Quality Assurance
- B. Validation
- C. Programming
- D. Quality Control

#### Answer: B

#### Explanation:

Validation is the process of ensuring that an electronic data processing system meets the sponsor's specifications for completeness, accuracy, reliability, and consistent performance. It involves systematic testing and documentation to demonstrate that the system functions as intended, especially in the context of capturing, processing, and managing clinical trial data.

GCP guidelines specify that validation of electronic systems is crucial to maintain data integrity and compliance with regulatory standards.

"Validation ensures that electronic data systems function according to the sponsor's requirements, maintaining data accuracy and reliability." Objectives:

Maintain data integrity and reliability.

Demonstrate system compliance with regulatory requirements.

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

A PI is reviewing the CRF for a recent subject visit and notices the participant's heart rate and temperature are not recorded. Which of the following study documentation practices was neglected?

- A. Attributable
- B. Contemporaneous
- C. Original
- D. Complete

#### Answer: D

#### Explanation:

The missing data indicates a lack of completeness in the study documentation. Completeness is a fundamental requirement in clinical trials, as all necessary information must be recorded accurately and in full. Missing vital signs such as heart rate and temperature can compromise the validity of the data and affect the study's outcomes.

GCP guidelines state that all data collected during the study must be complete, accurate, and consistent with source documents.

"Clinical trial documentation must be complete, containing all data as required by the protocol toensure data integrity." Objectives:

- \* Ensure comprehensive data recording.
- \* Maintain accuracy and completeness in study records.

#### **NEW QUESTION #56**

A trial subject was involved in a traffic accident. The emergency room (ER) doctor notifies the investigator that he wants to give the subject a blood transfusion. Blood transfusion is one of the prohibited treatments in the trial. How should the investigator respond?

- A. Advise the ER doctor to transfuse blood, and the PI should withdraw the subject from the trial.
- B. Ask the ER doctor not to transfuse blood and consider another treatment compliant with the protocol.
- C. Report this incident immediately to the sponsor and leave the treatment decision to them
- D. Advise the ER doctor to transfuse the blood, and the PI should report this incident to the sponsor.

#### Answer: D

#### Explanation:

The investigator must prioritize the subject's immediate health and safety. In a medical emergency, the appropriate response is to advise the ER doctor to proceed with the necessary medical intervention (blood transfusion). Afterward, the PI must promptly report the incident to the sponsor as a protocol deviation.

GCP guidelines emphasize that patient safety takes precedence over protocol requirements in emergency situations.

"In situations where immediate medical intervention is necessary to prevent harm, the investigator should ensure that the appropriate care is given and subsequently report the event as a deviation." Objectives:

- \* Prioritize patient safety in emergencies.
- \* Report protocol deviations promptly.

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

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