

# Free PDF Quiz 2026 Latest ACRP ACRP-CP New Practice Questions

## ACRP Practice Exam Questions and Answers

A subject is issued 120 tablets and is instructed to take 2 tablets 4 times a day. He returns 88 tablets on the morning of day 9 fasting for laboratory tests. What percent compliant is he? -

**ANSWER 50%**

To be eligible for a trial, the subjects must have liver function tests no greater than two times the upper limit normal and renal function tests no greater than three times the upper limit normal. All of the following are normal ranges for the trial:

AST 5-65

ALT 5-35

BUN 4-25

Creat 0.5-1.2

Amylase 56-190

Lipase 4-24

**ALK Phos 0-110 - ANSWER AST 130; ALT: 70; BUN 50; Creat 2.4**

A subject presents at a site with her husband after pre-qualifying on a phone screen. She states that she is legally blind and cannot read the ICF. A Braille ICF is not available. This subject is able to sign her name if her hand is guided to the signature line. Which of the following is the BEST course of action to obtain legal consent from the subject? - **ANSWER The subject and an impartial witness can sign the ICF after it is read to them and she verbally states her understanding.**

Which of the following is MOST useful for scheduling trial procedures? - **ANSWER trialschedule of events**

A subject is participating in a clinical trial where only the pharmacist and sponsor knows the identity of the IP. The pharmacist has no contact with the trial subject and the clinical team.

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## ACRP Certified Professional Exam Sample Questions (Q54-Q59):

### NEW QUESTION # 54

Access to study documentation for auditors and inspectors during an audit or inspection at a clinical trial site is the responsibility of the:

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

**Answer: D**

Explanation:

The Principal Investigator (PI) is responsible for providing access to study documentation during an audit or inspection. This includes regulatory files, participant records, and study logs. The PI ensures that auditors and inspectors have appropriate access while maintaining the confidentiality of subject data.

GCP guidelines clearly assign the responsibility for maintaining and granting access to trial documentation to the PI at the study site.

"The PI is responsible for ensuring that study-related documents are available for review during audits or inspections." Objectives:

- \* Maintain transparency during inspections.
- \* Ensure compliance with documentation requirements.

### NEW QUESTION # 55

In preparation for an upcoming site audit, whose responsibility is it to ensure study-related functions were conducted by qualified personnel?

- **A. Investigator**
- B. Sponsor
- C. CRA
- D. CRC

**Answer: A**

Explanation:

The Principal Investigator (PI) holds ultimate responsibility for ensuring that all study-related functions are conducted by qualified and trained personnel. The PI must verify that staff have the necessary qualifications and training to perform their assigned tasks as outlined in the protocol. This responsibility is crucial for maintaining compliance with GCP and ensuring data integrity.

According to GCP guidelines, the PI must ensure that all staff assisting with the trial are adequately trained and qualified for their roles.

"The investigator is responsible for ensuring that all persons assisting with the trial are qualified by education, training, and experience to perform their respective tasks." Objectives:

- \* Maintain compliance with GCP requirements.
- \* Ensure qualified personnel conduct study tasks.

### NEW QUESTION # 56

The IRB/IEC has decided to not approve a clinical trial. Who must they notify in writing?

- A. Sponsor
- B. Regulatory Agency
- C. CRC
- **D. PI**

**Answer: D**

Explanation:

When the IRB/IEC decides not to approve a clinical trial, they must notify the Principal Investigator (PI) in writing. This communication ensures that the PI is formally informed of the decision and can take appropriate actions, such as revising the protocol or addressing the reasons for disapproval.

According to GCP guidelines, the IRB/IEC must communicate any decision regarding the approval status of a study directly to the PI, as the PI is responsible for the conduct of the trial.

"The IRB/IEC should promptly notify the investigator in writing of its decision to approve or disapprove the proposed research activity." Objectives:

- \* Maintain clear communication between the IRB/IEC and the investigator.
- \* Ensure timely notification of decisions affecting the study.

#### NEW QUESTION # 57

A protocol inclusion criterion requires the serum magnesium at screening to be within the normal range. After the subject received IP, the CRC discovers the subject's screening magnesium level was below the normal range and the sub-investigator marked the lab sheet as not clinically significant. Which of the following should be done FIRST?

- A. Notify the regulatory authority.
- B. Withdraw the subject.
- C. Notify the subject.
- **D. Notify the sponsor.**

**Answer: D**

Explanation:

When a protocol deviation is identified, especially one involving inclusion criteria, the sponsor must be notified immediately. The sponsor will assess the deviation and determine whether the subject can continue in the study. Early notification ensures appropriate action and compliance with protocol and regulatory guidelines.

This answer aligns with GCP principles that mandate sponsor notification in case of protocol deviations, especially when they may impact participant safety or data integrity.

"Any deviation from the protocol that affects subject eligibility must be reported to the sponsor immediately for evaluation and guidance." Objectives:

- \* Maintain adherence to protocol inclusion criteria.
- \* Report deviations promptly for safety assessment.

#### NEW QUESTION # 58

An impartial witness should be present during the entire informed consent discussion when:

- **A. A legally acceptable representative is unable to read.**
- B. An interpreter is translating the consent form for a subject.
- C. A subject has been determined to be vulnerable.
- D. A parent/guardian is consenting for a minor subject.

**Answer: A**

Explanation:

An impartial witness is required when a legally acceptable representative (LAR) or the subject themselves cannot read. The witness ensures that the information is presented accurately and that the consent process is conducted ethically. The witness also signs the consent form to confirm that the subject or representative understands the study details.

GCP guidelines require an impartial witness to be present to confirm that the consent information is correctly conveyed and understood when the subject or LAR cannot read.

"An impartial witness is required when the subject or legally acceptable representative is unable to read, ensuring the consent process is transparent and ethically sound." Objectives:

- \* Protect the rights of individuals with literacy challenges.
- \* Maintain ethical standards in the consent process.

#### NEW QUESTION # 59

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