

# ACRP-CP Latest Exam Questions - ACRP-CP Valid Exam Topics

## 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 trial schedule 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 (Q24-Q29):

### NEW QUESTION # 24

A study sponsor approaches a facility about participating in their research study. The study sponsor requires use of social media as its sole method of recruitment. The site knows their institutional IRB/IEC does not approve of social media recruiting. How should the site respond?

- A. Use a central IRB/IEC.
- **B. Decline the study.**
- C. Rely on the sponsor to notify the IRB/IEC.
- D. Recruit for the study without use of social media.

**Answer: B**

Explanation:

If the IRB/IEC has a policy that does not permit social media recruiting, the site must adhere to these regulations. Proceeding with a method not approved by the IRB/IEC would violate compliance requirements, so declining the study is the correct course of action. The answer aligns with IRB/IEC regulations that prioritize ethical and compliant recruitment methods.

"Sites must follow the recruitment methods approved by their IRB/IEC to maintain compliance and ethical standards." Objectives:

- \* Adhering to ethical recruitment practices.
- \* Maintaining compliance with IRB/IEC policies.

### NEW QUESTION # 25

A site has reported multiple temperature excursions for an IP, primarily because the air conditioning (A/C) gets shut off after business hours. A separate A/C unit cannot be installed in the room where the IP is kept. What would be the MOST effective long-term mitigation strategy?

- A. Install an air cooler requiring regular water refills to maintain the room temperature.
- B. Return all IP and request the CRO/Sponsor to directly ship IP to participants.
- **C. Invest in a room temperature controlled IP cabinet and transfer IP to this unit.**
- D. Continue reporting temperature excursions per the pharmacy manual guidelines.

**Answer: C**

Explanation:

Investing in a temperature-controlled IP cabinet is the most effective and sustainable solution for maintaining IP stability. This cabinet can consistently regulate temperature without relying on external A/C systems, thereby minimizing the risk of excursions and ensuring compliance with storage requirements.

GCP guidelines state that IP must be stored under controlled conditions as specified by the protocol and product labeling.

"Temperature-controlled storage units should be used when site environmental conditions are not reliable to maintain IP stability."

Objectives:

- \* Ensure IP stability and compliance.
- \* Mitigate temperature excursion risks effectively.

### NEW QUESTION # 26

A protocol requires participants to take 1 tablet of IP per day. At each visit, participants are supplied with enough IP for 35 days. They are asked to return any unused IP at the next visit. One participant returns at the 1-month visit at 30 days with 10 tablets of unused IP and at the 2-month visit at 60 days with 12 tablets of unused IP. What is the participant's overall compliance?

- A. 80%
- B. 71%
- **C. 77%**
- D. 66%

**Answer: C**

Explanation:

Step 1: Calculate the total number of tablets dispensed:

\* Month 1: 35 tablets

\* Month 2: 35 tablets

\* Total: 70 tablets

Step 2: Calculate the number of tablets returned:

\* Month 1: 10 tablets

\* Month 2: 12 tablets

\* Total: 22 tablets

Step 3: Calculate the number of tablets taken:

\*  $70 - 22 = 48$  tablets

Step 4: Calculate compliance:

\*  $\text{Compliance} = (\text{Tablets Taken} / \text{Total Tablets}) \times 100$

\*  $\text{Compliance} = (48 / 70) \times 100 \# 68.57\%$

GCP guidelines require accurate calculation of compliance based on returned IP counts, ensuring proper dose administration monitoring.

"Compliance rates are calculated by comparing the number of tablets taken to the total number of tablets dispensed, considering the returned count." Objectives:

\* Monitor compliance with IP administration.

\* Ensure accurate calculation of adherence rates.

#### **NEW QUESTION # 27**

When assessing the monitoring needs for a study, sponsors should:

- **A. Ensure monitors have the scientific and/or clinical knowledge needed to monitor the trial adequately.**
- B. Permit PIs to select a monitor for their site as long as they are independent of the PI.
- C. Ensure monitoring visits are conducted at periodic intervals with a minimum of monthly monitoring visits.
- D. Use central monitoring instead of conducting physical monitoring visits at sites.

**Answer: A**

Explanation:

Sponsors must ensure that monitors are adequately qualified, possessing the necessary scientific and clinical knowledge to effectively oversee the trial. This ensures that monitors can accurately assess protocol compliance, data integrity, and participant safety. The quality of monitoring directly impacts the credibility of the trial outcomes.

GCP guidelines specify that monitors must be adequately trained and knowledgeable about the trial protocol, investigational product (IP), and clinical research standards.

"The sponsor must ensure that monitors have appropriate qualifications and training to conduct effective trial monitoring." Objectives:

\* Maintain data integrity through skilled monitoring.

\* Ensure patient safety and protocol compliance.

#### **NEW QUESTION # 28**

Who on the local site research study team is accountable for the unblinding documentation of IP?

- **A. PI**
- B. CRC
- C. Regulatory manager
- D. Pharmacist

**Answer: A**

Explanation:

The Principal Investigator (PI) is ultimately responsible for maintaining and documenting any unblinding events related to the investigational product (IP). This accountability ensures that any instance where the blind is broken is properly justified, documented, and reported to maintain trial integrity.

GCP guidelines state that the PI must oversee the unblinding process and ensure proper documentation to protect the validity of the trial data.

"The PI is responsible for ensuring that any unblinding of the investigational product is adequately documented and reported according to protocol." Objectives:

- \* Maintain the integrity of blinded studies.
- \* Properly document unblinding incidents.

## NEW QUESTION # 29

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