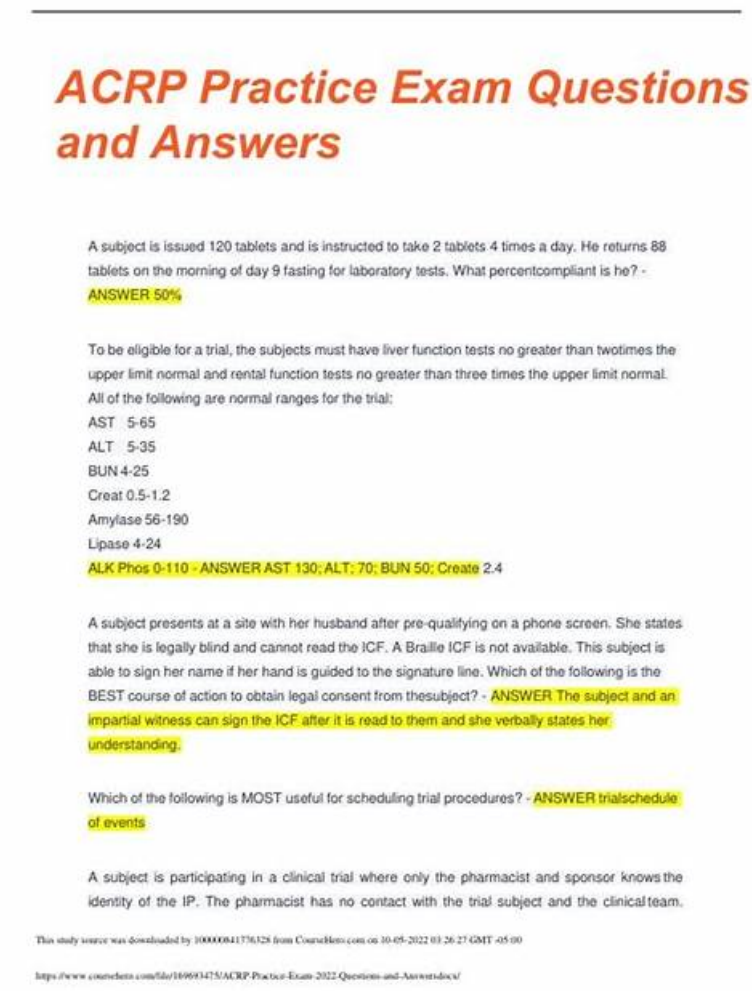
ACRP-CP Reliable Test Duration - ACRP-CP Original Questions



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 percentcompliant is he? - ANSWER 50%

To be eligible for a trial, the subjects must have liver function tests no greater than twotimes the upper limit normal and rental 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; Create 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 thesubject? - 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 clinicalteam.

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ACRP Certified Professional Exam Sample Questions (Q35-Q40):

NEW QUESTION # 35
An impartial witness should be present during the entire informed consent discussion when:

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

Answer: C

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 # 36
A clinical trial is conducted to measure the effectiveness of music therapy to reduce anxiety in intensive care unit patients. Patients are randomly assigned to receive headphones with music of their choice or headphones with white noise. The group receiving the white noise headphones is considered which type of control group?

- A. Alternate dose
- B. Active control
- C. Placebo
- D. No treatment

Answer: C

Explanation:
In this trial, the white noise group acts as a placebo control. While they are receiving an intervention (white noise), it is not the active therapeutic intervention (music therapy) being tested. Placebo controls help in assessing the effect of the active intervention by comparing it to a neutral or non-therapeutic alternative.
GCP guidelines state that a placebo control is a neutral intervention used to compare the effects of an active treatment.
"A placebo group is one that receives a neutral intervention, used to measure the efficacy of the active intervention by comparison." Objectives:
* Differentiate between active and placebo control groups.
* Evaluate therapeutic efficacy objectively.

NEW QUESTION # 37
Per the protocol, participants' blood creatinine level must be no greater than 2.5 times the upper limit of normal (0.7-1.2 mg/dL). What is the maximum creatinine level the participant can have and be eligible for the trial?

- A. 1.8 mg/dL
- B. 3.0 mg/dL
- C. 2.6 mg/dL
- D. 3.6 mg/dL

Answer: B

Explanation:
To calculate the maximum allowable creatinine level, multiply the upper limit of normal (1.2 mg/dL) by 2.5.
1.2 x 2.5 = 3.0 mg/dL
Therefore, the maximum creatinine level that a participant can have to remain eligible for the trial is 3.0 mg /dL.
GCP guidelines specify that eligibility criteria, including lab values, must be strictly followed to maintain protocol compliance.
"The protocol specifies that laboratory values must not exceed the defined limits to ensure participant safety and data integrity."
Objectives:
* Maintain accurate interpretation of laboratory criteria.
* Ensure compliance with protocol-defined inclusion/exclusion criteria.

NEW QUESTION # 38
A representative from a regulatory authority shows up unannounced at a research site. After confirming their credentials, the representative requested to view the entire records, including identifiable information, from study XYZ that was closed out. Which of the following should the site personnel do next?

- A. Consult with the IRB/IEC first.
- B. Allow access to the entire records.
- C. Deny the request until the sponsor approves.
- D. Redact subject identification for privacy protection.

Answer: B

Explanation:
Regulatory authorities have the legal right to inspect clinical trial records, including identifiable information, even if the study has been closed out. After verifying the inspector's credentials, the site personnel must grant access to all requested documents to ensure compliance with regulations.
According to GCP guidelines, regulatory authorities have the right to access trial-related documents and data during inspections.
"Investigators must grant access to study records when requested by regulatory authorities as part of their inspection rights."
Objectives:
* Ensure compliance with inspection requirements.
* Maintain transparency with regulatory authorities.

NEW QUESTION # 39
A double-blind randomized Phase III trial seeks to recruit 500 subjects in 2 years. At the end of the first year, 150 subjects have been enrolled. Monitoring reports from the first year note 50% of subjects screened were screen failures due to exclusionary lab values. What action should the sponsor take?

- A. Re-train investigators on recruitment obligations.
- B. Reduce the target sample size based on feedback from the sites.
- C. Allocate additional monitoring resources to the trial.
- D. Evaluate the screen failures to determine if the protocol needs revision.

Answer: D

Explanation:
The high rate of screen failures indicates that the inclusion/exclusion criteria may be too stringent or not appropriately defined. The sponsor should evaluate the reasons for these failures and determine whether the protocol needs adjustment. Revising the criteria may increase recruitment efficiency without compromising the scientific validity of the study.
GCP guidelines advise reviewing and possibly revising protocols when screen failure rates are significantly high to ensure feasible recruitment.
"If a high number of screen failures occurs, the sponsor should evaluate the inclusion/exclusion criteria and consider protocol revisions." Objectives:
* Improve recruitment efficiency.
* Adapt protocol criteria to real-world conditions.

NEW QUESTION # 40
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