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ACRP Certified Professional Exam Sample Questions (Q56-Q61):

NEW QUESTION # 56
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. 3.0 mg/dL
- B. 2.6 mg/dL
- C. 3.6 mg/dL
- D. 1.8 mg/dL

Answer: A

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 # 57
A protocol requires participants to take IP for 6 months. The protocol allows for any participants who are noncompliant to be replaced by enrolling additional participants, except if it is due to an AE. The investigator has enrolled 12 participants.
The status of the enrolled participants is as follows:
* 3 participants were withdrawn due to noncompliance
* 1 participant withdrew consent after experiencing severe nausea
* 1 participant had to discontinue IP for an unscheduled hospitalization
* 1 participant who is not returning for visits
* 2 participants completed the 6 months of treatment
* 4 participants currently on IP
How many participants should be replaced?

- A. 3 participants
- B. 6 participants
- C. 4 participants
- D. 5 participants

Answer: A

Explanation:
Since the protocol specifies that participants withdrawn due to an Adverse Event (AE) should not bereplaced, only the participants withdrawn for noncompliance (3 in total) should be replaced. The participant who withdrew consent due to severe nausea (an AE) and the one who discontinued IP due to hospitalization should not be replaced.
GCP guidelines specify that replacement of subjects should follow the protocol criteria, particularly when AEs are involved.
"Participants withdrawn due to AEs should not be replaced if the protocol stipulates this condition, while noncompliant participants may be replaced." Objectives:
* Follow protocol guidelines for participant replacement.
* Ensure compliance with study criteria.

NEW QUESTION # 58
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. Allow access to the entire records.
- B. Deny the request until the sponsor approves.
- C. Redact subject identification for privacy protection.
- D. Consult with the IRB/IEC first.

Answer: A

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 # 59
The PI did not record the relationship to IP in the medical chart when assessing an adverse event. The CRC noticed the omission and brought it to the PI's attention. How should this be addressed?

- A. The PI should amend the medical chart.
- B. The CRC should amend the medical chart.
- C. The CRC should write a note to file.
- D. The PI should notify the monitor.

Answer: A

Explanation:
The PI is responsible for ensuring accurate documentation of adverse events (AEs) in the medical chart, including their relationship to the investigational product (IP). If an omission is identified, the PI must correct it by making a dated and signed amendment to maintain data accuracy and completeness.
GCP guidelines state that the PI must maintain accurate and complete records, including the assessment of the relationship between AEs and the IP.
"The investigator must document the assessment of the relationship between the AE and the investigational product to ensure accurate clinical records." Objectives:
* Maintain accuracy in adverse event documentation.
* Ensure data integrity through appropriate corrections.

NEW QUESTION # 60
Which of the following is a conflict of interest for a PI conducting a study?

- A. A PI who is a key opinion leader, writes the protocol
- B. A PI that presents at an investigator meeting
- C. A PI who receives payment for the study
- D. A PI that votes on the IRB/IEC approval of the protocol

Answer: D

Explanation:
A Principal Investigator (PI) who is involved in voting on the IRB/IEC approval of their own protocol is considered to have a conflict of interest. The IRB/IEC must be independent and impartial when reviewing research proposals. Allowing the PI to vote on their own study compromises the ethical review process. To maintain unbiased decision-making, PIs must recuse themselves from such votes.
GCP guidelines emphasize the importance of avoiding conflicts of interest in the IRB/IEC decision-making process to maintain objectivity and ethical standards.
"A PI should not participate in voting or decision-making processes regarding the approval of their own study to avoid conflicts of interest." Objectives:
* Maintain impartiality in ethical review.
* Prevent conflicts of interest during IRB/IEC processes.

NEW QUESTION # 61
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