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ACRP Certified Professional Exam Sample Questions (Q108-Q113):

NEW QUESTION # 108
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. 2.6 mg/dL
- B. 1.8 mg/dL
- C. 3.6 mg/dL
- D. 3.0 mg/dL

Answer: D

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 # 109
Which document confirms the PI's agreement to permit auditing at the study site?

- A. Delegation Log
- B. IB
- C. Protocol
- D. ICF

Answer: D

Explanation:
The Informed Consent Form (ICF) typically includes a statement indicating that the participant's records may be reviewed by monitors, auditors, and regulatory authorities. This ensures transparency and compliance with regulatory requirements, allowing for audits and inspections when necessary.
This answer follows GCP guidelines which specify that the ICF should include consent for audits and inspections to protect subject confidentiality while ensuring data integrity.
"The ICF must include a statement allowing access to trial data for monitoring, auditing, and regulatory inspection purposes."
Objectives:
* Ensure informed consent for data access.
* Facilitate compliance with auditing requirements.

NEW QUESTION # 110
When determining whether a protocol deviation (PD) is reportable to the IRB/IEC, the PI should take into consideration whether the:

- A. Participant verbally agreed to the PD.
- B. Sponsor approved the PD.
- C. PD affected participant safety.
- D. PD affected participant recruitment.

Answer: C

Explanation:
The primary factor in determining whether a protocol deviation should be reported to the IRB/IEC is whether the deviation impacts participant safety or the integrity of the study data. Any deviation that could pose a risk to participants must be reported promptly to ensure ongoing ethical oversight.
GCP guidelines mandate reporting of any protocol deviations that affect safety or data integrity to the IRB /IEC.
"Protocol deviations that impact the safety of participants or the integrity of the study must be reported to the IRB/IEC." Objectives:
* Maintain participant safety.
* Ensure regulatory compliance through prompt reporting.

NEW QUESTION # 111

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. Rely on the sponsor to notify the IRB/IEC.
- C. Decline the study.
- D. Recruit for the study without use of social media.

Answer: C

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 # 112

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

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

Answer: D

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 # 113

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