




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ACRP CP Exam Actual Questions and Answers 100% Correct | Updated 2023-2024


1571 - Answer  IND application; Permit to do research on humans for the first time; has background info; and rationale; updated annually

1572 - Answer  Investigator statement; commitment, done nationally and internationally by sponsors intending to have marketing approval for IP


IB - Answer  Clinical and non-clinical data on the investigational product that is relevant to the study in human subjects; supplied prior to regulatory approval


Study type - Open Label - Answer  everyone knows the treatment


Study type - Single blind - Answer  one party knows Tx, usually the patient does not know but the monitoring team does

Study type - Double Blind - Answer  2 or more people are blinded, usually the patient and monitoring team do not know which drug is given.

A 3rd party unblinded pharmacist is used and an unblinded CRA is needed

Study Type - Double dummy - Answer  Use to blind similar Tx's; one is active and one is placebo. This occurs when the drug and placebo cannot be made identical (pill vs liquid)

Study Type - Parallel - Answer  Two groups of treatments. One group receives only treatment A and another group receives only treatment B

Study Type - Crossover - Answer  Usually Chronic disease; receives more than one Tx with a washout in between. A then B; could be randomized so the sequence changes

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ACRP Certified Professional Exam Sample Questions (Q98-Q103):

NEW QUESTION # 98

Source data/documentation should be:

- A. Attributable, legible, correct, original, accurate, and complete.
- B. Attributable, legible, correct, original, accurate, and clear.
- **C. Attributable, legible, contemporaneous, original, accurate, and complete.**
- D. Attributable, legible, contemporaneous, original, accurate, and clear.

Answer: C

Explanation:

Source data/documentation in clinical trials must meet the ALCOA-C standard: Attributable, Legible, Contemporaneous, Original, Accurate, and Complete. This ensures that data is credible, traceable to the source, and maintains integrity throughout the study. These attributes are essential for maintaining high- quality, reliable, and verifiable clinical trial records.

GCP guidelines mandate that source documentation should adhere to the ALCOA-C principles to maintain data integrity and reliability.

"Source data must be attributable, legible, contemporaneous, original, accurate, and complete to meet quality and compliance standards." Objectives:

- * Maintain data integrity and reliability.
- * Adhere to best practices in clinical documentation.

NEW QUESTION # 99

Who is responsible for the ongoing safety evaluation of the IP?

- A. PI
- B. IRB/IEC
- **C. Sponsor**
- D. Regulatory agency

Answer: C

Explanation:

The sponsor is primarily responsible for the ongoing safety evaluation of the investigational product (IP) throughout the clinical trial. This responsibility includes monitoring adverse events, reporting serious adverse events (SAEs) to regulatory authorities, and updating the Investigator's Brochure (IB) with relevant safety data.

According to GCP guidelines, the sponsor must continuously evaluate safety data and report findings to regulatory bodies as necessary.

"The sponsor is responsible for the continuous safety monitoring of the investigational product and for ensuring that new safety information is communicated to investigators and regulators." Objectives:

- * Ensure participant safety throughout the study.
- * Maintain accurate and timely reporting of safety data.

NEW QUESTION # 100

A monitor identifies multiple deviations from a protocol-defined timeline for study procedures. The monitor is unable to identify proof of PI review and assessment of the deviations. The monitor discusses the deviations with the PI, who initiates a CAPA. What is the purpose of this CAPA?

- A. To determine if the deviations invalidate the data
- **B. To establish a procedure for PI oversight of protocol deviations**
- C. To determine if a protocol amendment is needed
- D. To escalate corrective actions to the regulatory authority

Answer: B

Explanation:

A Corrective and Preventive Action (CAPA) plan is implemented to address deviations and prevent them from recurring. In this context, the purpose of the CAPA is to establish a procedure for the Principal Investigator (PI) to ensure proper oversight of protocol deviations. This ensures that all future deviations are appropriately managed, reviewed, and documented according to GCP standards.

The answer is verified from GCP guidelines which emphasize that CAPA should focus on identifying root causes and establishing processes to prevent future deviations.

"A CAPA plan must address the root cause and implement systematic actions to prevent the recurrence of protocol deviations."

Objectives:

- * Ensuring PI oversight in protocol adherence
- * Maintaining data integrity through systematic corrective actions

NEW QUESTION # 101

A PI on a study is a regular member of the IRB/IEC. Which of the following statements is TRUE regarding their participation in the IRB/IEC discussion and deliberation?

- A. They can attend the meeting, but should not vote/provide opinion on whether to approve the study.
- **B. They must recuse themselves from the meeting given their dual roles as IRB/IEC member and PI.**
- C. They can attend the meeting and can vote/provide opinion on whether to approve the study.
- D. They cannot be the PI on the clinical study due to conflict of interest.

Answer: B

Explanation:

If a PI is also a member of the IRB/IEC, they must recuse themselves from the meeting when their own study is being reviewed to avoid conflicts of interest. This practice preserves the objectivity and impartiality of the IRB/IEC's decisions.

The answer is verified based on IRB/IEC operational guidelines, which mandate that members with potential conflicts recuse themselves from discussions and voting.

"To maintain objectivity, IRB/IEC members who have a conflict of interest related to a study must recuse themselves from the review and decision-making process." Objectives:

- * Maintain impartiality in IRB/IEC decisions
- * Prevent conflicts of interest in clinical trial approval

NEW QUESTION # 102

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. 3.6 mg/dL
- **C. 3.0 mg/dL**
- D. 2.6 mg/dL

Answer: C

Explanation:

To calculate the maximum allowable creatinine level, multiply the upper limit of normal (1.2 mg/dL) by 2.5.

$$1.2 \times 2.5 = 3.0 \text{ mg/dL}$$

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.

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