

100% Pass Quiz 2026 Newest ACRP ACRP-CP: Exam ACRP Certified Professional Exam Revision Plan

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 (Q65-Q70):

NEW QUESTION # 65

A hospital site is being considered for a trial that requires the IP refrigerator to be continuously monitored using the sponsor-provided Wi-Fi-enabled thermometer. The hospital's Wi-Fi connectivity is inconsistent. During site selection, how should the CRA proceed?

- A. Accept this site and implement and maintain QA and QC systems with written SOPs.
- B. Accept this site and plan to undertake routine safety evaluations of the IP.
- C. Before accepting this site, report the risk to the trial sponsor and await their decision.
- D. Before accepting this site, ensure the refrigerator is calibrated and functioning properly.

Answer: C

Explanation:

Since the Wi-Fi connectivity is inconsistent, the CRA must assess the risk and report it to the trial sponsor for a decision. Accepting the site without proper risk evaluation may compromise the monitoring of the investigational product (IP) storage conditions, affecting trial integrity.

The answer follows GCP guidelines that emphasize assessing potential risks during site selection and involving the sponsor when critical issues arise.

"When faced with site-specific issues that may affect data integrity or product safety, the CRA should consult with the sponsor before making a final decision." Objectives:

- * Ensuring proper site selection
- * Managing potential risks proactively

NEW QUESTION # 66

A clinical trial is conducted to test the effect of an investigational drug on cholesterol levels. Statistical analysis will be performed to:

- A. Fail to reject the null hypothesis that the drug has an effect on cholesterol levels.
- B. Fail to reject the alternative hypothesis that the drug has an effect on cholesterol levels.
- C. Reject the null hypothesis that the drug has no effect on cholesterol levels.
- D. Reject the alternative hypothesis that the drug has no effect on cholesterol levels.

Answer: C

Explanation:

The purpose of statistical analysis in a clinical trial is to evaluate whether the data supports rejecting the null hypothesis, which typically states that there is no effect or difference. If the analysis finds a statistically significant result, the null hypothesis is rejected, indicating that the investigational drug has an effect on cholesterol levels.

The answer follows statistical principles in clinical trials, where the null hypothesis is rejected if evidence shows a significant difference or effect.

"In hypothesis testing, rejecting the null hypothesis indicates that the treatment effect is statistically significant." Objectives:

- * Understand hypothesis testing in clinical research.
- * Interpret statistical outcomes accurately.

NEW QUESTION # 67

A deferred consent can take place in which of the following situations?

- A. Only when the PI approves such a consent process, regardless of the emergency situation described in the protocol.
- B. In an emergency situation only, even when this process is not described in the protocol, but the sponsor approves the consent process.
- C. Only when the PI approves such a consent process immediately prior to patient enrollment, regardless of the situation being classed as emergency.
- D. In an emergency situation only, when this process is described in the protocol and has received permission from the ethics committee.

Answer: D

Explanation:

Deferred consent is permissible in emergency situations where immediate intervention is necessary and obtaining prior consent is not feasible. However, this practice must be explicitly described in the protocol and approved by the ethics committee. This ensures that the rights of patients are protected even in urgent circumstances.

GCP guidelines emphasize that deferred consent is only allowed when pre-approved by the ethics committee as part of the protocol for emergency interventions.

"In emergencies, deferred consent is permitted only if outlined in the protocol and approved by the ethics committee, ensuring compliance with ethical standards." Objectives:

- * Protect patient rights in emergency research.
- * Ensure ethical approval for deferred consent.

NEW QUESTION # 68

After the completion or termination of a clinical trial, who should store the enrollment log?

- A. CRO
- B. Sponsor
- C. Regulatory authority
- D. PI

Answer: D

Explanation:

The Principal Investigator (PI) is responsible for maintaining and securely storing essential documents, including the enrollment log, after the completion or termination of a clinical trial. This ensures that all participant-related records are retained for audit or inspection as per regulatory requirements.

This answer is consistent with GCP guidelines, which specify that the PI is accountable for retaining essential trial documents at the study site.

"The investigator should maintain records of trial participants, including the enrollment log, as part of the essential documents for trial conduct." Objectives:

- * Maintain data integrity and compliance with record-keeping requirements.
- * Ensure secure and accessible storage of participant information.

NEW QUESTION # 69

A study protocol must contain which of the following elements?

- A. Data management plan
- B. Chemical structure of the IP
- C. Participant reimbursement details
- D. Description of statistical methods

Answer: D

Explanation:

A clinical study protocol must include a clear description of the statistical methods to be used in analyzing the collected data. This ensures that the analysis plan is predefined, unbiased, and statistically sound. The statistical methodology must address how the primary and secondary endpoints will be evaluated.

GCP guidelines require that the protocol clearly outlines statistical methods to ensure accurate and unbiased analysis of trial data.

"The protocol should include a detailed description of the statistical methods employed to ensure the validity of the trial results."

Objectives:

- * Maintain transparency in data analysis.
- * Ensure scientific rigor in evaluating study outcomes.

NEW QUESTION # 70

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