




ACRP - High Hit-Rate ACRP-CP - ACRP Certified Professional Exam Test Dates

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 (Q32-Q37):

NEW QUESTION # 32

A serious unexpected ADR is one:

- A. Severity and nature of the reaction is consistent with protocol.
- B. That does not need to be reported to the IRB/IEC.
- C. That results in the death of the subject.
- D. Where the severity of the reaction is not consistent with IB.

Answer: D

Explanation:

A serious unexpected adverse drug reaction (ADR) is characterized by an event that is not consistent with the information provided in the Investigator's Brochure (IB). Such reactions may indicate new risks associated with the investigational product and warrant immediate reporting to the sponsor and regulatory authorities.

This answer follows the ICH E6(R2) GCP guidelines, which specify the criteria for reporting serious and unexpected adverse events.

"An unexpected adverse drug reaction is one whose nature or severity is not consistent with the applicable product information (e.g., IB)." Objectives:

- * Understanding classification of ADRs
- * Ensuring timely and accurate reporting of unexpected events

NEW QUESTION # 33

An impartial witness should be present during the entire informed consent discussion when:

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

Answer: A

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 # 34

Which of the following should be reviewed and evaluated by qualified experts to assess implications for the safety of the trial subjects?

- A. Emerging animal toxicological and clinical data
- B. Sample collection storage, disposal, and shipment requirements
- C. Project feasibility considerations
- D. PI roles and responsibilities

Answer: A

Explanation:

Qualified experts should evaluate emerging animal toxicological and clinical data to assess potential safety implications for trial

subjects. These data are critical in identifying potential risks, adverse effects, or safety concerns before exposing human subjects to the investigational product. Early detection of safety issues through expert evaluation helps protect participant well-being. GCP guidelines stress the importance of expert assessment of preclinical and clinical data to identify risks and ensure participant safety.

"Emerging toxicological and clinical data should be carefully reviewed by qualified experts to identify safety concerns before clinical use." Objectives:

- * Ensure participant safety through expert data analysis.
- * Identify potential safety risks early in the trial process.

NEW QUESTION # 35

At a close-out visit, which document should be retained only at the site?

- A. IP accountability
- **B. Subject identification code list**
- C. Treatment allocation
- D. Final trial close-out monitoring report

Answer: B

Explanation:

The subject identification code list, which links the participant's unique code to their personal information, must be retained only at the site. This list ensures confidentiality and is necessary for identifying participants during follow-up. It is not shared with the sponsor to protect participant privacy.

GCP guidelines mandate that the subject identification code list remains at the site to ensure confidentiality and compliance with data protection regulations.

"The subject identification code list must be securely stored at the site to maintain participant confidentiality." Objectives:

- * Safeguard participant confidentiality.
- * Maintain compliance with data protection policies.

NEW QUESTION # 36

A written description of a trial in which the clinical and statistical description, presentations, and analyses are fully integrated into a single document is called a:

- A. Clinical Study Protocol
- B. IDMC/DSMB Report
- **C. Clinical Study Report**
- D. Investigator Brochure

Answer: C

Explanation:

A Clinical Study Report (CSR) is a comprehensive document that integrates clinical and statistical data from a clinical trial. It provides a complete and detailed account of the study's methods, results, and conclusions, including safety and efficacy analyses. The CSR is prepared at the end of the trial to summarize the data for regulatory submission and scientific publication.

GCP guidelines state that the CSR should integrate both clinical and statistical information to provide a comprehensive overview of the trial's outcomes.

"The Clinical Study Report contains a complete and integrated presentation of clinical and statistical findings from a clinical trial."

Objectives:

- * Document trial outcomes comprehensively.
- * Facilitate regulatory review and scientific dissemination.

NEW QUESTION # 37

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