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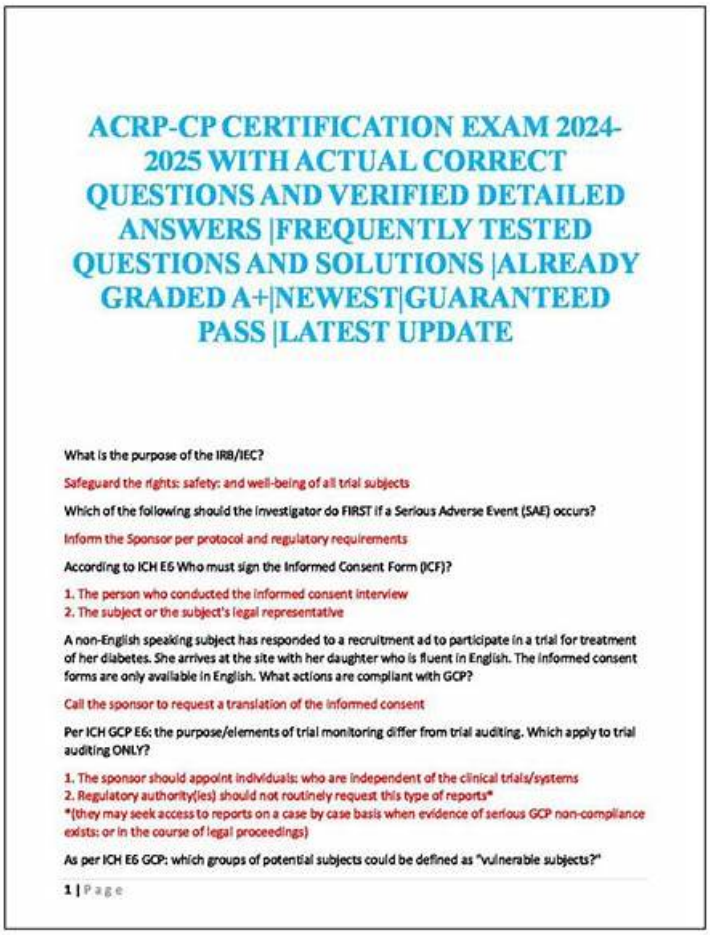
ACRP-CP CERTIFICATION EXAM 2024-2025 WITH ACTUAL CORRECT QUESTIONS AND VERIFIED DETAILED ANSWERS |FREQUENTLY TESTED QUESTIONS AND SOLUTIONS |ALREADY GRADED A+|NEWEST|GUARANTEED PASS |LATEST UPDATE

What is the purpose of the IRB/IEC?

Safeguard the rights: safety: and well-being of all trial subjects

Which of the following should the investigator do FIRST if a Serious Adverse Event (SAE) occurs?

Inform the Sponsor per protocol and regulatory requirements

According to ICH E6 Who must sign the Informed Consent Form (ICF)?

1. The person who conducted the informed consent interview
2. The subject or the subject's legal representative

A non-English speaking subject has responded to a recruitment ad to participate in a trial for treatment of her diabetes. She arrives at the site with her daughter who is fluent in English. The informed consent forms are only available in English. What actions are compliant with GCP?

Call the sponsor to request a translation of the informed consent

Per ICH GCP E6: the purpose/elements of trial monitoring differ from trial auditing. Which apply to trial auditing ONLY?

1. The sponsor should appoint individuals: who are independent of the clinical trials/systems
2. Regulatory authority(ies) should not routinely request this type of reports*
*(they may seek access to reports on a case by case basis when evidence of serious GCP non-compliance exists: or in the course of legal proceedings)

As per ICH E6 GCP: which groups of potential subjects could be defined as "vulnerable subjects?"

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ACRP Certified Professional Exam Sample Questions (Q58-Q63):

NEW QUESTION # 58
The composition of an IDMC/DSMB should include which one of the following?

- A. A lead PI for the study
- B. A member from the IRB/IEC
- C. A clinical scientist who is knowledgeable in the appropriate discipline
- D. A sponsor representative who is knowledgeable about the study's unblinded information

Answer: C

Explanation:
An Independent Data Monitoring Committee (IDMC) or Data and Safety Monitoring Board (DSMB) should include clinical scientists who are knowledgeable in the relevant medical and scientific areas. Their role is to objectively assess the ongoing safety data and efficacy of the investigational product, ensuring that participants' safety is not compromised.
GCP guidelines emphasize the need for experienced clinical scientists on IDMC/DSMBs to ensure that safety data is interpreted accurately and professionally.
"IDMC/DSMB should comprise independent experts, including clinical scientists, who have the expertise to evaluate safety and efficacy data objectively." Objectives:
* Ensure impartial evaluation of safety data.
* Maintain scientific integrity in monitoring clinical trials.

NEW QUESTION # 59
The sponsor must report a serious unexpected AE to the regulatory authorities within a maximum of:

- A. 7 calendar days
- B. 8 calendar days
- C. 30 calendar days
- D. 15 calendar days

Answer: D

Explanation:
The sponsor is required to report serious unexpected adverse events (SAEs) to the regulatory authorities within 15 calendar days from the date of awareness. This reporting period is mandated to ensure that any new safety information that may affect the risk/benefit profile of the investigational product (IP) is promptly communicated, thereby protecting participant safety.
GCP guidelines specify that serious, unexpected, and related AEs must be reported to regulatory authorities within 15 days of being known to the sponsor.
"Serious unexpected adverse reactions that may affect the safety profile of the IP must be reported within 15 calendar days to the regulatory authorities." Objectives:
* Ensure timely reporting of safety information.
* Protect the safety of trial participants.

NEW QUESTION # 60
After the site qualification visit report has been finalized, it must be:

- A. Kept in the CRO/sponsor's trial master file.
- B. Stored in the sponsor's budgets and contracts file.
- C. Included in the PI's regulatory file.
- D. Sent to the IRB/IEC for review and approval.

Answer: A

Explanation:
The finalized site qualification visit report must be maintained in the sponsor's trial master file (TMF) as part of the essential

documents. The TMF serves as the repository for all documents that demonstrate compliance with the protocol and regulatory requirements. Storing the report in the TMF ensures traceability and documentation of the site's suitability for conducting the trial. GCP guidelines require that site qualification visit reports be included in the trial master file to maintain comprehensive documentation of site assessments.
"Finalized site qualification visit reports must be stored in the sponsor's trial master file to ensure proper documentation and compliance." Objectives:
* Maintain documentation of site qualifications.
* Ensure compliance through comprehensive record-keeping.

NEW QUESTION # 61
Who on the local site research study team is accountable for the unblinding documentation of IP?

- A. Pharmacist
- B. Regulatory manager
- C. CRC
- D. PI

Answer: D

Explanation:
The Principal Investigator (PI) is ultimately responsible for maintaining and documenting any unblinding events related to the investigational product (IP). This accountability ensures that any instance where the blind is broken is properly justified, documented, and reported to maintain trial integrity.
GCP guidelines state that the PI must oversee the unblinding process and ensure proper documentation to protect the validity of the trial data.
"The PI is responsible for ensuring that any unblinding of the investigational product is adequately documented and reported according to protocol." Objectives:
* Maintain the integrity of blinded studies.
* Properly document unblinding incidents.

NEW QUESTION # 62
In order to conduct open-label, parallel group clinical trials according to sound scientific principles, which of the following design elements should be included?

- A. Privacy controls
- B. Randomization
- C. Blinding
- D. Placebo-controlled

Answer: B

Explanation:
Randomization is a key element in open-label, parallel group clinical trials to reduce selection bias and ensure that participant allocation is not influenced by investigators. Despite the absence of blinding in open-label studies, randomization maintains the validity and reliability of the results by evenly distributing confounding factors between groups.
GCP guidelines recommend randomization as a core element in clinical trial design to ensure unbiased allocation of participants.
"Randomization in parallel group trials helps minimize selection bias and ensures the comparability of intervention groups."
Objectives:
* Maintain scientific rigor through randomization.
* Minimize selection bias in clinical studies.

NEW QUESTION # 63
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