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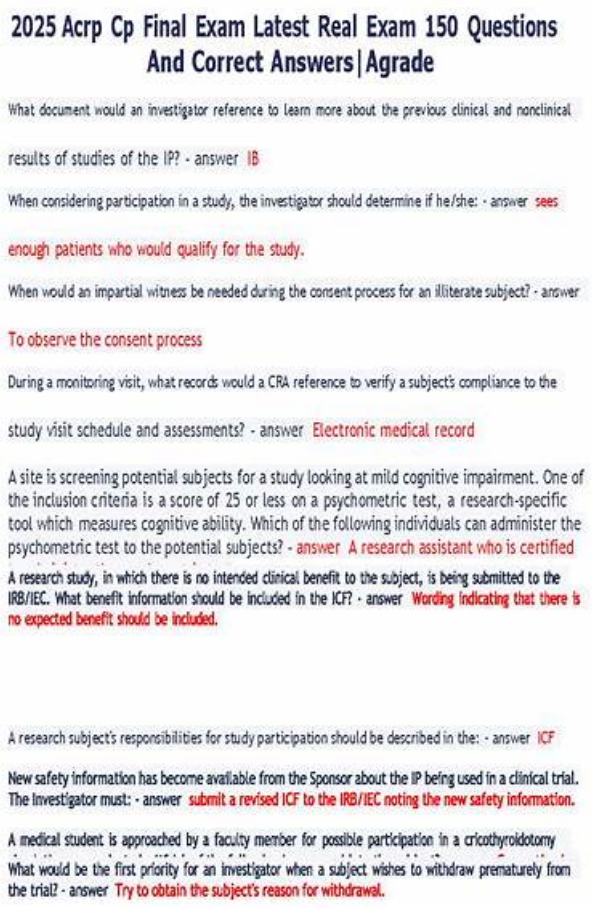

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What document would an investigator reference to learn more about the previous clinical and nonclinical results of studies of the IP? - answer IB

When considering participation in a study, the investigator should determine if he/she: - answer sees enough patients who would qualify for the study.

When would an impartial witness be needed during the consent process for an illiterate subject? - answer To observe the consent process

During a monitoring visit, what records would a CRA reference to verify a subject's compliance to the study visit schedule and assessments? - answer Electronic medical record

A site is screening potential subjects for a study looking at mild cognitive impairment. One of the inclusion criteria is a score of 25 or less on a psychometric test, a research-specific tool which measures cognitive ability. Which of the following individuals can administer the psychometric test to the potential subjects? - answer A research assistant who is certified

A research study, in which there is no intended clinical benefit to the subject, is being submitted to the IRB/IEC. What benefit information should be included in the ICF? - answer Wording indicating that there is no expected benefit should be included.

A research subject's responsibilities for study participation should be described in the: - answer ICF

New safety information has become available from the Sponsor about the IP being used in a clinical trial. The investigator must: - answer submit a revised ICF to the IRB/IEC noting the new safety information.

A medical student is approached by a faculty member for possible participation in a cricothyroidotomy What would be the first priority for an investigator when a subject wishes to withdraw prematurely from the trial? - answer Try to obtain the subject's reason for withdrawal.

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ACRP Certified Professional Exam Sample Questions (Q85-Q90):

NEW QUESTION # 85
When designing a clinical trial, why is it important to define the study population?

- A. To determine where to conduct the study
- B. To support the study objectives
- C. To determine the study objectives
- D. To support subject recruitment to the study

Answer: B

Explanation:
Defining the study population is crucial because it ensures that the trial targets the appropriate group for evaluating the investigational product (IP). A well-defined population supports the study objectives by providing reliable and interpretable data that can address the research questions.
GCP guidelines emphasize the need for a clearly defined study population to ensure the generalizability and accuracy of trial results.
"The study population must be clearly defined to ensure that the trial data are relevant and applicable to the intended patient group."
Objectives:
* Enhance the scientific validity of clinical trial outcomes.
* Support the accurate interpretation of efficacy and safety data.

NEW QUESTION # 86
A site is starting up a Phase III trial. They have received IRB/IEC approval and have scheduled the SIV. The site cannot begin enrolling subjects until:

- A. The DSMB meets and the first DSMB meeting report has been issued.
- B. The site receives approval from the medical monitor to begin enrolling.
- C. A signed clinical trial agreement between the site and sponsor is in place.
- D. The CRA has performed source document review and verification at the site.

Answer: C

Explanation:
Before a clinical trial site can begin enrolling participants, there must be a signed clinical trial agreement (CTA) between the site and the sponsor. This agreement outlines the responsibilities, financial arrangements, and expectations between both parties, ensuring that the trial is conducted in compliance with regulatory and ethical standards.
GCP guidelines require that a formal agreement be in place before trial initiation to protect the rights and obligations of both the sponsor and the site.
"Before subject enrollment can commence, the sponsor and site must finalize a clinical trial agreement, establishing legal and ethical commitments." Objectives:
* Ensure proper contractual arrangements before trial initiation.
* Protect legal rights and obligations of involved parties.

NEW QUESTION # 87
SAEs must be reported immediately by the site to the:

- A. Regulatory agency.
- B. DSMB/IDMC.
- C. Sponsor.
- D. IRB/IEC.

Answer: C

Explanation:
Serious Adverse Events (SAEs) must be reported immediately to the sponsor. The sponsor then assesses the severity, causality, and potential impact on the study and decides whether further reporting to regulatory authorities and IRB/IEC is required. Immediate reporting ensures that appropriate actions are taken to safeguard participant safety.
GCP guidelines specify that the site must notify the sponsor immediately about any SAE to ensure timely safety assessment and

reporting.
"Sites must report all serious adverse events immediately to the sponsor, who will then determine the appropriate regulatory and ethical reporting requirements." Objectives:
* Ensure rapid reporting of serious adverse events.
* Maintain safety monitoring during the trial.

NEW QUESTION # 88
A sponsor wants to transfer duties to a CRO. Which of the following statements is the MOST correct?

- A. The IRB/IEC must approve the transfer of duties to a CRO.
- B. All duties transferred to a CRO should be specified in writing.
- C. Any trial-related duties can be documented as transferred by verbal agreement.
- D. Regulatory authorities must be notified promptly of the transfer of any duties to a CRO.

Answer: B

Explanation:
When a sponsor transfers specific tasks to a Contract Research Organization (CRO), it must be documented in writing. This formal documentation clearly delineates responsibilities and ensures that both parties are aware of their roles and obligations. Verbal agreements are not sufficient forregulatory compliance.
ICH E6(R2) GCP guidelines mandate that all delegated tasks must be documented formally to ensure clarity and compliance.
"The sponsor should document in writing any responsibilities transferred to a CRO to ensure clear delineation of roles." Objectives:
* Maintain clear documentation of delegated tasks.
* Ensure compliance with regulatory standards.

NEW QUESTION # 89
Which statement does NOT represent a study monitor's responsibilities?

- A. Verify that the PI has adequate qualifications and resources to conduct the study.
- B. Report serious adverse events to the IRB/IEC.
- C. Provide communication between the sponsor and the PI.
- D. Check the accuracy and completeness of case report forms with source documents.

Answer: B

Explanation:
It is not the monitor's responsibility to report serious adverse events (SAEs) to the IRB/IEC. This responsibility typically falls on the PI or the sponsor. Monitors focus on data accuracy, protocol compliance, and communication between the site and the sponsor.
The answer follows GCP standards where the monitor's role is clearly defined, excluding SAE reporting to IRB/IEC.
"Monitors are responsible for verifying data accuracy and communicating with the sponsor but not for direct reporting of SAEs to the IRB/IEC." Objectives:
* Distinguish between the responsibilities of monitors and investigators
* Clarify SAE reporting protocols

NEW QUESTION # 90
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