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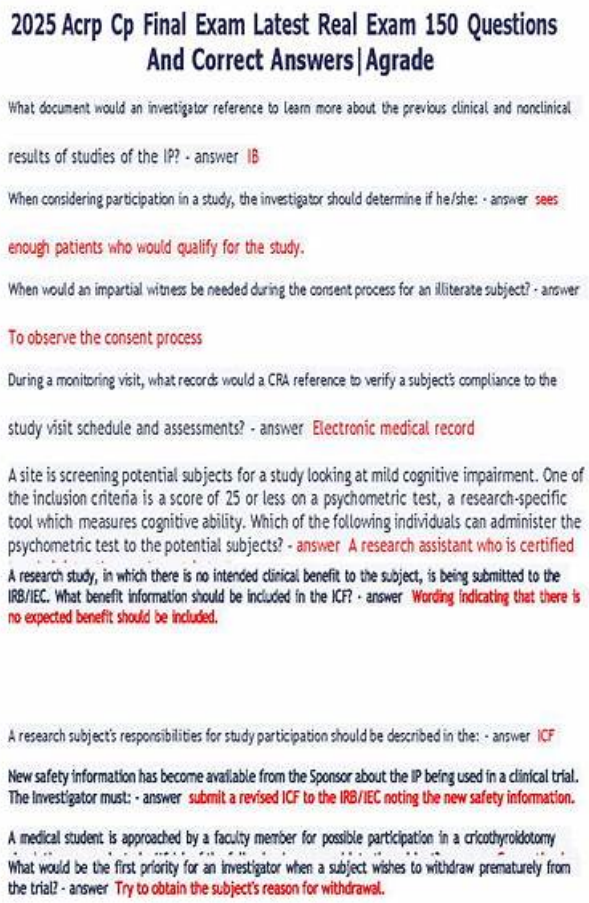
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What document would an investigator reference to learn more about the previous clinical and nonclinical results of studies of the IP? - answer IB

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 (Q27-Q32):

NEW QUESTION # 27
Which of the following reports should be retained in participant charts?

- A. IRB/IEC progress reports
- B. DSMB/IDMC reports
- C. Lab reports
- D. Safety reports

Answer: C

Explanation:
Lab reports contain individual participant data relevant to their health status and the study's outcomes. These reports are essential for verifying subject safety and evaluating the effects of the investigational product (IP).
Therefore, they must be retained in the participant's medical records.
According to GCP guidelines, participant charts must include laboratory data as part of the essential documents to ensure accurate and complete clinical records.
"Lab reports must be maintained as part of the participant's chart for safety monitoring and data verification." Objectives:
* Maintain comprehensive medical records for each participant.
* Ensure availability of clinical data for audit and review.

NEW QUESTION # 28
An investigator participating in a multicenter clinical trial has had 2 of the 4 subjects admitted to the emergency room for life-threatening infections. The investigator made the decision to stop treatment with IP and test for infections in the remaining subjects. What are the NEXT steps the investigator should take?

- A. Update the IB to add the risk of infection and submit to the sponsor for approval.
- B. Discontinue current subjects from the study and monitor subjects for any anticipated safety events.
- C. Notify the sponsor of the change in study plan and submit the deviation to the IRB/IEC for review.
- D. Add the risk of infection to the ICF and submit to the IRB/IEC for review.

Answer: C

Explanation:
The investigator must promptly notify the sponsor about the observed safety concerns and the decision to stop the IP administration. This constitutes a protocol deviation that must be reported tothe IRB/IEC for ethical oversight. It is essential to document the deviation accurately and seek guidance on whether to continue or modify the study procedures.
GCP guidelines require that significant deviations impacting participant safety be reported to both the sponsor and the IRB/IEC for appropriate review and action.
"Significant safety-related deviations must be reported promptly to the sponsor and IRB/IEC to ensure proper oversight and participant protection." Objectives:
Ensure prompt reporting of safety concerns.
Maintain compliance with ethical oversight requirements.

NEW QUESTION # 29
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. Project feasibility considerations
- C. PI roles and responsibilities
- D. Sample collection storage, disposal, and shipment requirements

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 # 30
A potential subject is interested in a new clinical trial and would like to learn more about the risks and benefits of participation. Where can they find this information?

- A. ICF
- B. IB
- C. Package insert
- D. Protocol

Answer: A

Explanation:
The Informed Consent Form (ICF) contains comprehensive information about the potential risks and benefits of participation in a clinical trial. It is a legally required document that ensures that subjects make an informed decision before enrollment.
The answer is consistent with GCP guidelines which mandate that the ICF clearly outlines the risks and benefits of participation to protect participant rights.
"The ICF should include a clear explanation of potential risks and benefits to ensure informed decision- making by the participant." Objectives:
* Ensure informed decision-making by potential subjects.
* Provide transparent risk-benefit information.

NEW QUESTION # 31
The PI should ensure that source data is:

- A. Printed directly from the EMR.
- B. On worksheets that are provided by the sponsor.
- C. Kept on site for a minimum of 2 years.
- D. Accurately reflected in the eCRFs.

Answer: D

Explanation:
The PI is responsible for ensuring that the source data is accurately recorded in the electronic Case Report Forms (eCRFs). This accurate transposition of data is critical to maintaining data integrity and ensuring that the data collected at the site is consistent with the reported clinical outcomes.
GCP guidelines specify that source data should be accurate, legible, and directly reflected in the CRFs to maintain consistency and reliability.
"The PI must ensure that the source data are accurately and completely recorded in the eCRFs to maintain data integrity." Objectives:
* Ensure accurate data transposition from source to CRF.
* Maintain high standards of data quality and reliability.

NEW QUESTION # 32
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