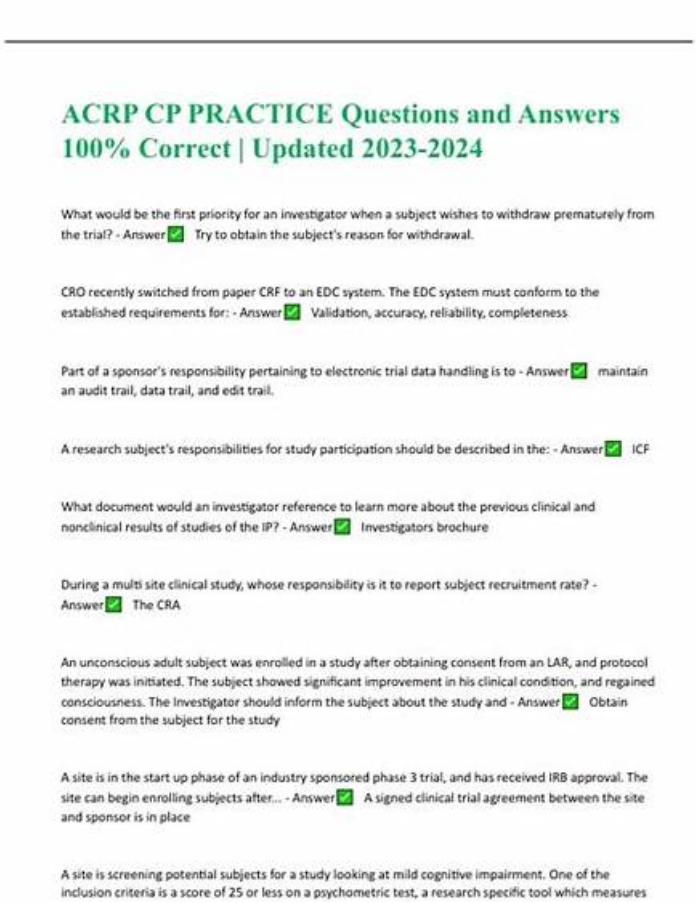
ACRP-CP認定資格試験、ACRP-CP日本語版問題解説



ACRP CP PRACTICE Questions and Answers
100% Correct | Updated 2023-2024

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.

CRO recently switched from paper CRF to an EDC system. The EDC system must conform to the established requirements for: - Answer✅ Validation, accuracy, reliability, completeness

Part of a sponsor's responsibility pertaining to electronic trial data handling is to - Answer✅ maintain an audit trail, data trail, and edit trail.

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

What document would an investigator reference to learn more about the previous clinical and nonclinical results of studies of the IP? - Answer✅ Investigators brochure

During a multi site clinical study, whose responsibility is it to report subject recruitment rate? - Answer✅ The CRA

An unconscious adult subject was enrolled in a study after obtaining consent from an LAR, and protocol therapy was initiated. The subject showed significant improvement in his clinical condition, and regained consciousness. The Investigator should inform the subject about the study and - Answer✅ Obtain consent from the subject for the study

A site is in the start up phase of an industry sponsored phase 3 trial, and has received IRB approval. The site can begin enrolling subjects after... - Answer✅ A signed clinical trial agreement between the site and sponsor is in place

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

さらに、Jpexam ACRP-CPダンプの一部が現在無料で提供されています：https://drive.google.com/open?id=1yIa3Zo5VJ7fH7jUUIvzxr9QPm5tZuCh-

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テストが来るのを静かに待っている場合は、目を覚まして、別の方法でACRP-CP試験を受ける準備ができている必要があります。最近のACRP-CPガイド急流の効果が資格試験を通じて受験者の秘密兵器になったことを示した後、ACRP-CPトレーニング資料を勉強して「テストデータ」を書くことがあなたの選択に最適です。ACRP-CPガイドトレントのユーザーは、ACRP-CP試験で予期しない結果を得ることができます。

>> ACRP-CP認定資格試験 <<

ACRP ACRP-CP日本語版問題解説 & ACRP-CP無料模擬試験

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ACRP Certified Professional Exam 認定 ACRP-CP 試験問題 (Q96-Q101):

質問 # 96
Which of the following should be reviewed and evaluated by qualified experts to assess implications for the safety of the trial subjects?

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

正解：C

解説：
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.

質問 # 97
A clinical trial is conducted to measure the effectiveness of music therapy to reduce anxiety in intensive care unit patients. Patients are randomly assigned to receive headphones with music of their choice or headphones with white noise. The group receiving the white noise headphones is considered which type of control group?

- A. No treatment
- B. Alternate dose
- C. Active control
- D. Placebo

正解：D

解説：
In this trial, the white noise group acts as a placebo control. While they are receiving an intervention (white noise), it is not the active therapeutic intervention (music therapy) being tested. Placebo controls help in assessing the effect of the active intervention by comparing it to a neutral or non-therapeutic alternative.
GCP guidelines state that a placebo control is a neutral intervention used to compare the effects of an active treatment.
"A placebo group is one that receives a neutral intervention, used to measure the efficacy of the active intervention by comparison." Objectives:
* Differentiate between active and placebo control groups.
* Evaluate therapeutic efficacy objectively.

質問 # 98
A site has reported multiple temperature excursions for an IP, primarily because the air conditioning (A/C) gets shut off after business hours. A separate A/C unit cannot be installed in the room where the IP is kept.
What would be the MOST effective long-term mitigation strategy?

- A. Invest in a room temperature controlled IP cabinet and transfer IP to this unit.
- B. Install an air cooler requiring regular water refills to maintain the room temperature.
- C. Return all IP and request the CRO/Sponsor to directly ship IP to participants.
- D. Continue reporting temperature excursions per the pharmacy manual guidelines.

正解：A

解説：
Investing in a temperature-controlled IP cabinet is the most effective and sustainable solution for maintaining IP stability. This cabinet can consistently regulate temperature without relying on external A/C systems, thereby minimizing the risk of excursions and ensuring compliance with storage requirements.
GCP guidelines state that IP must be stored under controlled conditions as specified by the protocol and product labeling.
"Temperature-controlled storage units should be used when site environmental conditions are not reliable to maintain IP stability."
Objectives:
* Ensure IP stability and compliance.
* Mitigate temperature excursion risks effectively.

質問 # 99
In addition to members who collectively have the qualifications and experience to review and evaluate the science, medical aspects, and ethics of the proposed trial, it is recommended that the IRB/IEC should include:

- A. A total of five members.
- B. One member whose primary area of interest is in the same scientific area.
- C. One member of the site's QA group.
- D. One member who is independent of the institution/trial site.

正解：D

解説：
The IRB/IEC should include at least one member who is not affiliated with the institution or trial site to ensure impartiality and objectivity in the review process. This helps maintain ethical oversight without internal biases influencing the decisions.
This answer is based on ICH E6(R2) GCP guidelines, which mandate the inclusion of non-affiliatedmembers to uphold the integrity of the ethical review process.
"The IRB/IEC should include at least one member who is not associated with the institution to provide an unbiased perspective."
Objectives:
* Maintain impartiality in ethical review.
* Ensure diverse representation within the IRB/IEC.

質問 # 100
All site financial matters pertaining to a trial are listed in what document?

- A. Informed consent form
- B. Protocol
- C. Signed contract
- D. Financial disclosure

正解：C

解説：
All financial agreements, including compensation, budgeting, and payment terms related to the conduct of a clinical trial, are documented in the signed contract between the sponsor and the site. This contract outlines the financial responsibilities and ensures transparency and compliance.
GCP guidelines stipulate that financial matters related to the conduct of a trial are to be formally documented in contractual agreements.
"The financial aspects of a clinical trial must be outlined in the signed agreement between the sponsor and the site, ensuring clear understanding of compensation and obligations." Objectives:
* Ensure financial transparency and accountability.
* Maintain compliance with contractual obligations.

質問 # 101
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優秀な資料を利用すれば、短時間の準備をしても、高得点で試験に合格することができます。ACRP-CP試験の

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ACRP-CP日本語版問題解説: https://www.jpexam.com/ACRP-CP_exam.html

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