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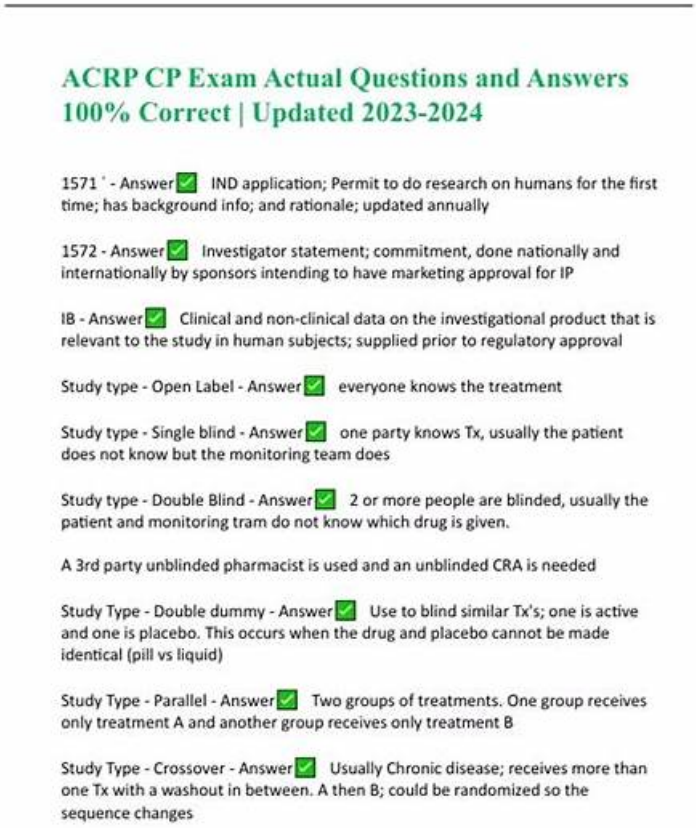

ACRP CP Exam Actual Questions and Answers
100% Correct | Updated 2023-2024

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 tram 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

P.S. Free 2025 ACRP ACRP-CP dumps are available on Google Drive shared by VerifiedDumps: https://drive.google.com/open?id=1Bpk5fElVoNirXN707b9R-I1BsrDOISnw

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ACRP Certified Professional Exam Sample Questions (Q121-Q126):

NEW QUESTION # 121
When determining whether a protocol deviation (PD) is reportable to the IRB/IEC, the PI should take into consideration whether the:

- A. Participant verbally agreed to the PD.
- B. PD affected participant recruitment.
- C. Sponsor approved the PD.
- D. PD affected participant safety.

Answer: D

Explanation:
The primary factor in determining whether a protocol deviation should be reported to the IRB/IEC is whether the deviation impacts participant safety or the integrity of the study data. Any deviation that could pose a risk to participants must be reported promptly to ensure ongoing ethical oversight.
GCP guidelines mandate reporting of any protocol deviations that affect safety or data integrity to the IRB
/IEC.
"Protocol deviations that impact the safety of participants or the integrity of the study must be reported to the IRB/IEC." Objectives:
* Maintain participant safety.
* Ensure regulatory compliance through prompt reporting.

NEW QUESTION # 122
A study sponsor approaches a facility about participating in their research study. The study sponsor requires use of social media as its sole method of recruitment. The site knows their institutional IRB/IEC does not approve of social media recruiting. How should the site respond?

- A. Rely on the sponsor to notify the IRB/IEC.
- B. Use a central IRB/IEC.
- C. Decline the study.
- D. Recruit for the study without use of social media.

Answer: C

Explanation:
If the IRB/IEC has a policy that does not permit social media recruiting, the site must adhere to these regulations. Proceeding with a method not approved by the IRB/IEC would violate compliance requirements, so declining the study is the correct course of action. The answer aligns with IRB/IEC regulations that prioritize ethical and compliant recruitment methods.
"Sites must follow the recruitment methods approved by their IRB/IEC to maintain compliance and ethical standards." Objectives:
* Adhering to ethical recruitment practices.
* Maintaining compliance with IRB/IEC policies.

NEW QUESTION # 123
A PI is being considered for an industry-sponsored study. The PI sees approximately 20 patients per month who meet the study criteria. The PI does not have access to a Positron Emission Tomography (PET) scanner, which is required for the protocol. The PI is already taking part in three other studies. Should the Sponsor choose this PI?

- A. No, the PI does not have the resources to perform all protocol-required procedures.
- B. Yes, the PI can perform other imaging scans instead of the PET scans.
- C. Yes, the PI has a sufficient patient population to take part in this study.

- D. No, the PI is taking part in too many ongoing studies to participate in this study.

Answer: A

Explanation:
The PI lacks access to a PET scanner, a required element for conducting the study according to the protocol.
Without this essential equipment, the PI cannot fully meet the study requirements, making it unsuitable for the sponsor to select this site. Compliance with the protocol's technical requirements is crucial for the trial's success.
GCP guidelines state that investigators must have access to all necessary facilities and equipment to conduct the trial as outlined in the protocol.
"The investigator must have adequate resources, including access to required equipment, to perform the study as specified."
Objectives:
Ensure site readiness for protocol requirements.
Prevent protocol deviations due to inadequate resources.

NEW QUESTION # 124
Who is responsible for defining, establishing, and allocating all trial-related duties and functions prior to initiating a trial?

- A. CRO
- B. Investigator
- C. Sponsor
- D. IRB/IEC

Answer: C

Explanation:
The sponsor is responsible for defining, establishing, and allocating all trial-related duties and functions before the trial begins. This includes outlining roles and responsibilities in collaboration with investigators, CROs, and other stakeholders. Proper delegation ensures the trial is conducted according to protocol and regulatory requirements.
This answer is verified based on GCP guidelines, which clearly state that sponsors are responsible for the organization and management of trial-related tasks.
"The sponsor is responsible for allocating duties and functions related to the conduct of the trial, ensuring compliance with regulatory and ethical standards." Objectives:
* Clarify the sponsor's role in clinical trial management
* Define responsibilities in trial planning

NEW QUESTION # 125
After enrolling and treating a few subjects on an investigator-initiated trial, the PI would like to include a subject diary for each trial subject to capture their activities and experiences on the trial regimen. After the PI has generated a diary, what should the PI do next?

- A. Submit the diary to the sponsor for approval.
- B. Submit the diary to the IRB/IEC for approval.
- C. No approval is necessary: give the diary to each subject.
- D. Submit the diary to the regulatory authority for approval.

Answer: B

Explanation:
Any new data collection tool introduced during a clinical trial, including subject diaries, must be reviewed and approved by the IRB/IEC before implementation. This ensures that the new tool is ethically appropriate, respects subject privacy, and aligns with the approved protocol.
This answer aligns with ICH E6(R2) GCP guidelines, which mandate IRB/IEC approval for any new or modified subject-related documents introduced during a trial.
"All changes in study documents, including subject diaries, must be submitted for IRB/IEC review to ensure compliance with ethical standards." Objectives:
* Maintain compliance with IRB/IEC requirements.
* Ensure ethical handling of subject data.

NEW QUESTION # 126
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