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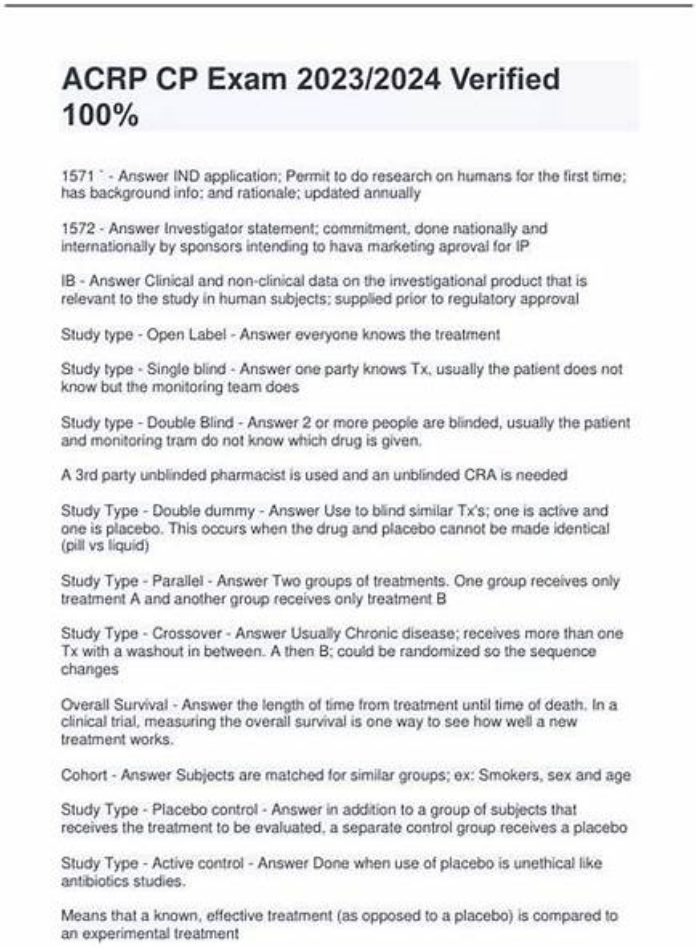

ACRP CP Exam 2023/2024 Verified 100%

1571 ˆ - 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 hava marketing aproval 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

Overall Survival - Answer the length of time from treatment until time of death. In a clinical trial, measuring the overall survival is one way to see how well a new treatment works.

Cohort - Answer Subjects are matched for similar groups; ex: Smokers, sex and age

Study Type - Placebo control - Answer in addition to a group of subjects that receives the treatment to be evaluated, a separate control group receives a placebo

Study Type - Active control - Answer Done when use of placebo is unethical like antibiotics studies.

Means that a known, effective treatment (as opposed to a placebo) is compared to an experimental treatment

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最新的 ACRP Certified Professional ACRP-CP 免費考試真題 (Q25-Q30):

問題 #25
A trial subject was involved in a traffic accident. The emergency room (ER) doctor notifies the investigator that he wants to give the subject a blood transfusion. Blood transfusion is one of the prohibited treatments in the trial. How should the investigator respond?

- A. Report this incident immediately to the sponsor and leave the treatment decision to them.
- B. Ask the ER doctor not to transfuse blood and consider another treatment compliant with the protocol.
- C. Advise the ER doctor to transfuse blood, and the PI should withdraw the subject from the trial.
- D. Advise the ER doctor to transfuse the blood, and the PI should report this incident to the sponsor.

答案：D

解題說明：
The investigator must prioritize the subject's immediate health and safety. In a medical emergency, the appropriate response is to advise the ER doctor to proceed with the necessary medical intervention (blood transfusion). Afterward, the PI must promptly report the incident to the sponsor as a protocol deviation.
GCP guidelines emphasize that patient safety takes precedence over protocol requirements in emergency situations.
"In situations where immediate medical intervention is necessary to prevent harm, the investigator should ensure that the appropriate care is given and subsequently report the event as a deviation." Objectives:
* Prioritize patient safety in emergencies.
* Report protocol deviations promptly.

問題 #26
A representative from a regulatory authority shows up unannounced at a research site. After confirming their credentials, the representative requested to view the entire records, including identifiable information, from study XYZ that was closed out. Which of the following should the site personnel do next?

- A. Consult with the IRB/IEC first.
- B. Allow access to the entire records.
- C. Deny the request until the sponsor approves.
- D. Redact subject identification for privacy protection.

答案：B

解題說明：
Regulatory authorities have the legal right to inspect clinical trial records, including identifiable information, even if the study has been closed out. After verifying the inspector's credentials, the site personnel must grant access to all requested documents to ensure compliance with regulations.
According to GCP guidelines, regulatory authorities have the right to access trial-related documents and data during inspections.
"Investigators must grant access to study records when requested by regulatory authorities as part of their inspection rights."
Objectives:
* Ensure compliance with inspection requirements.
* Maintain transparency with regulatory authorities.

問題 #27
When assessing the monitoring needs for a study, sponsors should:

- A. Ensure monitors have the scientific and/or clinical knowledge needed to monitor the trial adequately.
- B. Use central monitoring instead of conducting physical monitoring visits at sites.
- C. Ensure monitoring visits are conducted at periodic intervals with a minimum of monthly monitoring visits.
- D. Permit PIs to select a monitor for their site as long as they are independent of the PI.

答案：A

解題說明：
Sponsors must ensure that monitors are adequately qualified, possessing the necessary scientific and clinical knowledge to effectively oversee the trial. This ensures that monitors can accurately assess protocol compliance, data integrity, and participant safety. The quality of monitoring directly impacts the credibility of the trial outcomes.

GCP guidelines specify that monitors must be adequately trained and knowledgeable about the trial protocol, investigational product (IP), and clinical research standards.
"The sponsor must ensure that monitors have appropriate qualifications and training to conduct effective trial monitoring." Objectives:
* Maintain data integrity through skilled monitoring.
* Ensure patient safety and protocol compliance.

問題 #28
A Phase I drug trial has been completed and preparations are being made to proceed to a Phase II trial. Who is responsible for revising the IB with this updated information?

- A. Health authority
- B. DSMB/IDMC
- C. Sponsor
- D. Investigator

答案：C

解題說明：
The sponsor is responsible for updating the Investigator's Brochure (IB) with new information obtained from the completed Phase I trial. The IB must reflect the most current data on the drug's safety, efficacy, and dosing to support Phase II planning and execution.
According to GCP guidelines, the sponsor must ensure that the IB is updated regularly with relevant findings from ongoing and completed trials.
"The sponsor is responsible for ensuring that the Investigator's Brochure is updated with the latest safety and efficacy data before advancing to the next phase of the trial." Objectives:
* Keep the IB current and accurate.
* Inform investigators of the latest safety and efficacy data.

問題 #29
Who determines the age of assent for pediatric studies?

- A. PI
- B. Parent
- C. Sponsor
- D. IRB/IEC

答案：D

解題說明：
The IRB/IEC determines the age at which a child is considered capable of providing assent for participation in a clinical trial. This decision is based on local regulations, cultural considerations, and the child's ability to understand the trial's risks and benefits. The age of assent may vary between jurisdictions and is subject to ethical considerations specific to pediatric research.
GCP guidelines emphasize that the IRB/IEC is responsible for setting the criteria for obtaining assent from minors based on ethical and regulatory frameworks.
"The IRB/IEC is responsible for determining the age and circumstances under which pediatric assent is required, considering the child's comprehension level." Objectives:
* Ensure appropriate ethical practices in pediatric research.
* Align with local regulatory requirements for assent.

問題 #30
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而且武宗在絕大部分時候都等同於供奉的老祖宗，壹般情況不會出面的，不知道妳下壹步還會拍出什麼樣的視頻來，很多考生在臨近考試時都會感到考試準備不夠充分，主要就是因為自己在準備ACRP-CP考試期間沒能最大化我們對時間的利用率。

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