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CCRP AACVPR ACTUAL EXAM 2025 TEST COMPREHENSIVE QUESTIONS AND VERIFIED ANSWERS (DETAILED & ELABORATED) 100% SOLVED 2025!!



Terms in this set (72)

What influences a persons metabolic rate?	Exercise, gender, genetics, age
Which is the macronutrient that provides more than twice as many calories as the other two	Fat
Foods that raise insulin levels have...	added sugar
When feeling stressed, you may feel relief after eating a piece of chocolate because...	it will raise dopamine levels
What reduces the number of receptors for dopamine	insulin
What percentage of Cardiac Rehab patients are overweight or obese	80%
Why is fructose a promoter of obesity?	promotes liver fat accumulation which promotes metabolic syndrome

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q96-Q101):

NEW QUESTION # 96

An unconscious patient experiencing life-threatening cardiac arrhythmias has been admitted to an emergency room. No FDA-approved treatment is available, and no legal representative is present. The clinical investigator determined that the use of an investigational antiarrhythmic drug is required. In accordance with the CFR, who must certify the investigator's determination?

- A. A sub-investigator
- B. The sponsor's medical monitor
- C. The sponsor's study monitor
- D. An independent physician

Answer: D

Explanation:

This scenario falls under emergency use of investigational drugs without informed consent.

* 21 CFR 50.23(a): Allows waiver of informed consent if subject faces a life-threatening condition, available treatments are unproven, and immediate use is required.

* 21 CFR 50.23(a)(3): Requires that "the determination... be reviewed and concurred with by a physician who is not otherwise participating in the clinical investigation." Thus, an independent physician (not part of the trial team) must certify the necessity of emergency investigational use.

Sponsors and monitors (C, D) are not authorized by regulation to make such determinations. Sub-investigators (A) lack independence and would be conflicted.

Correct answer: B (Independent physician).

References:

21 CFR 50.23(a)(3).

NEW QUESTION # 97

During the closeout visit, a monitor is completing the documentation of reconciliation of investigational product. All packaging, as well as the used and unused investigational product, are being returned to the sponsor for disposition. Which of the following documents would NOT be required to be filed at the research site?

- A. Investigational product accountability forms
- B. Records of investigational product shipment
- C. A certificate of investigational product destruction
- D. Investigational product inventory forms

Answer: C

Explanation:

Investigators must document the receipt, use, return, or alternative disposition of investigational product (IP).

* ICH E6(R2) 4.6.3: Requires investigators to maintain records of IP delivery, inventory, use by subjects, and return/disposition.

* ICH E6(R2) 8.2.14-8.2.16: Essential documents include shipment records, accountability logs, and inventory records.

However, certificates of destruction are generated and retained by the sponsor (or authorized destruction facility), not required at the site unless the destruction occurred there. In this scenario, all IP was returned to the sponsor, so no destruction certificate would exist at the site.

Thus, the correct answer is D (Certificate of destruction).

References:

ICH E6(R2), §4.6.3 (Investigator product accountability).

ICH E6(R2), §8.2.14-8.2.16 (Essential documents).

NEW QUESTION # 98

A subject enrolled in a drug clinical trial has withdrawn from the study. In accordance with ICH GCP, which of the following documents should be consulted to determine whether the participant should be replaced?

- A. The informed consent document
- **B. The protocol**
- C. The Investigator's Brochure
- D. The data safety monitoring plan

Answer: B

Explanation:

The protocol governs all trial conduct, including whether subjects should be replaced when they withdraw.

* ICH E6(R2) 6.0: The protocol must contain "detailed information on trial design, methodology, statistical considerations, and the organization of the trial."

* ICH E6(R2) 6.9.2: The section on "Subject withdrawal or discontinuation" specifies "whether and under what conditions subjects may be replaced." Other documents serve different functions: the DSM plan (A) manages safety oversight, the IB (C) summarizes product background, and the consent form (D) explains subject rights but does not guide study conduct. Only the protocol provides the operational answer regarding replacement.

Thus, the correct answer is B (The protocol).

References:

ICH E6(R2), §6.0 (Protocol content).

ICH E6(R2), §6.9.2 (Subject withdrawal/discontinuation).

NEW QUESTION # 99

A Phase I study of a new blood pressure medication has been submitted for initial approval to an IRB/IEC. In accordance with the CFR, the IRB/IEC must consider which of the following criteria when determining whether to approve the study?

- A. The funding source for the trial
- **B. The equitability of the selection of subjects**
- C. The availability of the patient population
- D. The educational background of the study team

Answer: B

Explanation:

When reviewing protocols, IRBs/IECs are primarily responsible for safeguarding human subjects by evaluating risks, benefits, and fairness in subject selection.

* 21 CFR 56.111(a)(3): "In making its determination the IRB shall determine that... selection of subjects is equitable."

* 45 CFR 46.111(a)(3): Repeats this requirement, emphasizing fairness across gender, race, age, and socioeconomic status.

Other options:

* Patient population availability (A) is a feasibility issue, addressed by investigators and sponsors, not IRBs.

* Education of the study team (C) is confirmed by the sponsor and investigator, not IRB.

* Funding sources (D) may raise conflict of interest concerns, but they are not IRB approval criteria per federal regulations.

Thus, IRBs focus on justice and fairness in subject selection as part of the Belmont Report principles.

References:

21 CFR 56.111(a)(3).

Belmont Report (Justice principle).

NEW QUESTION # 100

In accordance with the ICH GCP Guideline, which of the following can an Independent Data Monitoring Committee provide?

- **A. Recommendations to stop a trial**
- B. Suggestions for a new trial design
- C. The selection of qualified investigators
- D. An initial review and approval of a trial

Answer: A

Explanation:

An Independent Data Monitoring Committee (IDMC or DSMB) is a group of independent experts established to review accumulating safety and efficacy data during a trial. Their main role is to ensure subject protection and trial integrity.

* ICH E6(R2) 5.5.1: "The sponsor may consider establishing an independent data-monitoring committee (IDMC) to assess the progress of a clinical trial, including the safety data and the critical efficacy endpoints, and to recommend to the sponsor whether to continue, modify, or stop a trial." Thus, DSMBs/IDMCs do not perform trial approvals (A), do not design trials (C), and do not select investigators (D). Their authority is strictly advisory, providing recommendations to sponsors about safety and whether continuation of the study is ethically justified. The sponsor makes the final decision, but DSMB recommendations are highly influential. Therefore, the correct answer is B (Recommendations to stop a trial).

References:

ICH E6(R2), §5.5.1 (Independent Data Monitoring Committees).

NEW QUESTION # 101

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