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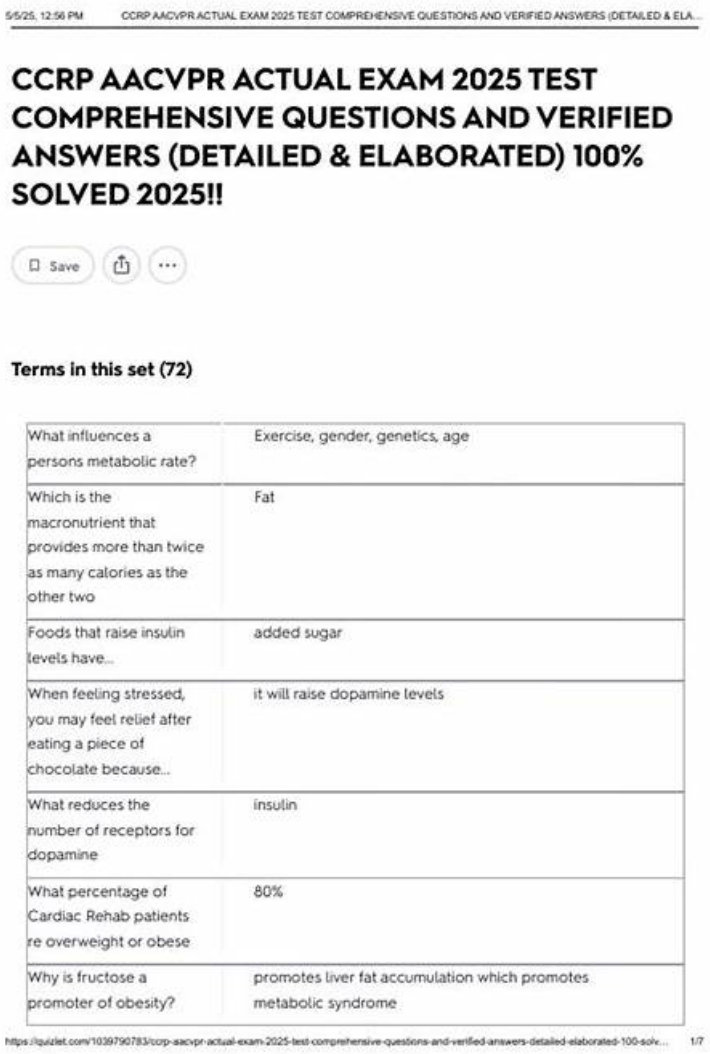

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CCRP AACVPR ACTUAL EXAM 2025 TEST COMPREHENSIVE QUESTIONS AND VERIFIED ANSWERS (DETAILED & ELABORATED) 100% SOLVED 2025!!

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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 re overweight or obese	80%
Why is fructose a promoter of obesity?	promotes liver fat accumulation which promotes metabolic syndrome

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SOCRA CCRP Exam Syllabus Topics:

Topic	Details

Topic 1	• Research Study Start-Up: This section of the exam measures the skills of Clinical Research Coordinators and covers the initial planning and setup of a clinical trial. It involves coordinating the development of the study protocol, ensuring it considers ethical guidelines and regulatory pathways like IND or IDE. It also includes creating essential study documents like informed consent forms and case report forms. The domain covers obtaining necessary approvals from stakeholders like the IRB and sponsor, selecting study sites, training staff, and ensuring the study's compliance with various laws. Additionally, it involves obtaining the research product and preparing all necessary tools and documentation for the study's commencement.|Research Study Implementation: This section of the exam measures the skills of Clinical Research Associates and covers the active management and execution of the clinical trial. It focuses on following the study protocol and standard operating procedures, managing the investigational product, and ensuring ongoing regulatory compliance. The domain includes identifying, documenting, and reporting any study anomalies such as adverse events or protocol deviations. It also involves managing subject recruitment, consent, and retention, as well as maintaining all study records and essential documents. Furthermore, it covers communicating with all study stakeholders and participating in study audits to ensure quality and adherence to regulations.
Topic 2	• Research Study Closure: This section of the exam measures the skills of Clinical Research Coordinators and covers the activities required to properly conclude a clinical trial. It involves participating in the study closeout visit to verify documentation and account for the investigational product. The domain also includes developing and submitting final closure reports to the IRB, study sponsor, regulatory authorities, and clinicaltrials.gov. Finally, it covers the procedures for archiving study records.

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q105-Q110):

NEW QUESTION # 105
While reviewing site records during a monitoring visit, a monitor can cite which of the following as a site violation of informed consent regulations?

- A. A copy of the consent document was not provided to a subject
- B. A subject's signature is missing on the copy of the summary of the short form consent
- C. Only the signatures of the person obtaining consent and the witness appear on the copy of the summary of the short form consent
- D. The sponsor-generated informed consent template is missing required elements

Answer: A

Explanation:
Providing acopy of the signed consent formto subjects is a mandatory requirement.
* 21 CFR 50.27(a):"A copy shall be given to the person signing the form."
* ICH E6(R2) 4.8.11:Reinforces that "a copy of the signed and dated written informed consent form should be given to the subject."
Failure to provide this copy constitutes adirect violation of informed consent regulations.
Other issues:
* A & C concern proper short form process but do not invalidate informed consent if a copy was provided.
* D concerns sponsor template, but the site's responsibility is ensuring use of IRB-approved version.
Correct answer:B.

References:
21 CFR 50.27(a).
ICH E6(R2), §4.8.11.

NEW QUESTION # 106
During an audit for a Phase II IND study, the auditor identified unreported serious protocol deviations. Which party must take prompt action to ensure compliance?

- A. The investigator
- B. The CRO
- C. The sponsor
- D. The IRB/IEC chair

Answer: C

Explanation:
The sponsor holds ultimate responsibility for trial oversight and compliance.
* ICH E6(R2) 5.20.1:If noncompliance is discovered, the sponsor must "take prompt action to secure compliance" and, if necessary, terminate participation of the investigator/institution.
* 21 CFR 312.56(b):Sponsors must ensure proper conduct and report investigators who fail to comply to the FDA and IRB.
While investigators commit to protocol adherence, once deviations are identified,the sponsor must actto safeguard subjects and trial validity.
References:ICH E6(R2) §5.20.1; 21 CFR 312.56(b).

NEW QUESTION # 107
Before approving a research protocol, an IRB/IEC must determine compliance with which of the following requirements?

- A. A plan for the publication of study results is in place
- B. The selection of subjects is equitable
- C. The sponsor is qualified to provide oversight of the trial
- D. The investigator has adequate access to patients eligible for the trial

Answer: B

Explanation:
IRB/IEC review focuses onethical protection of human subjects. Equitable subject selection is a cornerstone principle.
* 45 CFR 46.111(a)(3):"In order to approve research... the IRB shall determine that:Selection of subjects is equitable."
* ICH E6(R2) 3.1.2:"The IRB/IEC should safeguard the rights, safety, and well-being of all trial subjects... with particular attention to trials that may include vulnerable subjects." Publication plans (A) are not required by IRBs. Access to patients (C) and sponsor qualifications (D) are evaluated by sponsors, not IRBs. The IRB's role is ensuring fairness, minimizing coercion, and protecting vulnerable populations.
Thus, the correct answer isB (The selection of subjects is equitable).
References:
45 CFR 46.111(a)(3) (Equitable subject selection).
ICH E6(R2), §3.1.2 (IRB/IEC role).

NEW QUESTION # 108
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 data safety monitoring plan
- C. The protocol
- D. The Investigator's Brochure

Answer: C

Explanation:

Theprotocolgoverns 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 theprotocolprovides the operational answer regarding replacement.
Thus, the correct answer isB (The protocol).
References:
ICH E6(R2), §6.0 (Protocol content).
ICH E6(R2), §6.9.2 (Subject withdrawal/discontinuation).

NEW QUESTION # 109
An investigator is working with a new sponsor to submit a cardiovascular trial to the IRB/IEC. In accordance with the ICH GCP Guidelines, which parties should sign the protocol to confirm agreement that the trial will be conducted as agreed?

- A. The sponsor and the FDA
- B. The sponsor and the IRB/IEC
- C. The investigator/institution and the delegated site staff
- D. The investigator/institution and the sponsor

Answer: D

Explanation:
Theprotocol signature pagedocuments agreement between the sponsor and the investigator/institution to conduct the trial in compliance with ICH GCP, the protocol, and regulatory standards.
* ICH E6(R2) 8.2.2 (Signed protocol and amendments):Requires "the sponsor and investigator /institution to sign the protocol and amendments, confirming agreement."
* ICH E6(R2) 4.5.1:"The investigator should conduct the trial in compliance with the protocol agreed to by the sponsor and, if required, approved by the regulatory authority(ies) and by the IRB/IEC." The sponsor-investigator signatures ensure shared accountability for subject protection, data integrity, and adherence to trial methodology. Neither delegated staff (B) nor IRB/IEC (C) nor FDA (D) sign protocols.
These bodies approve or oversee, but do not formally enter into execution of the protocol.
Thus, the correct answer isA (The investigator/institution and the sponsor).
References:
ICH E6(R2), §8.2.2 (Signed protocol and amendments).
ICH E6(R2), §4.5.1 (Investigator compliance with protocol).

NEW QUESTION # 110
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