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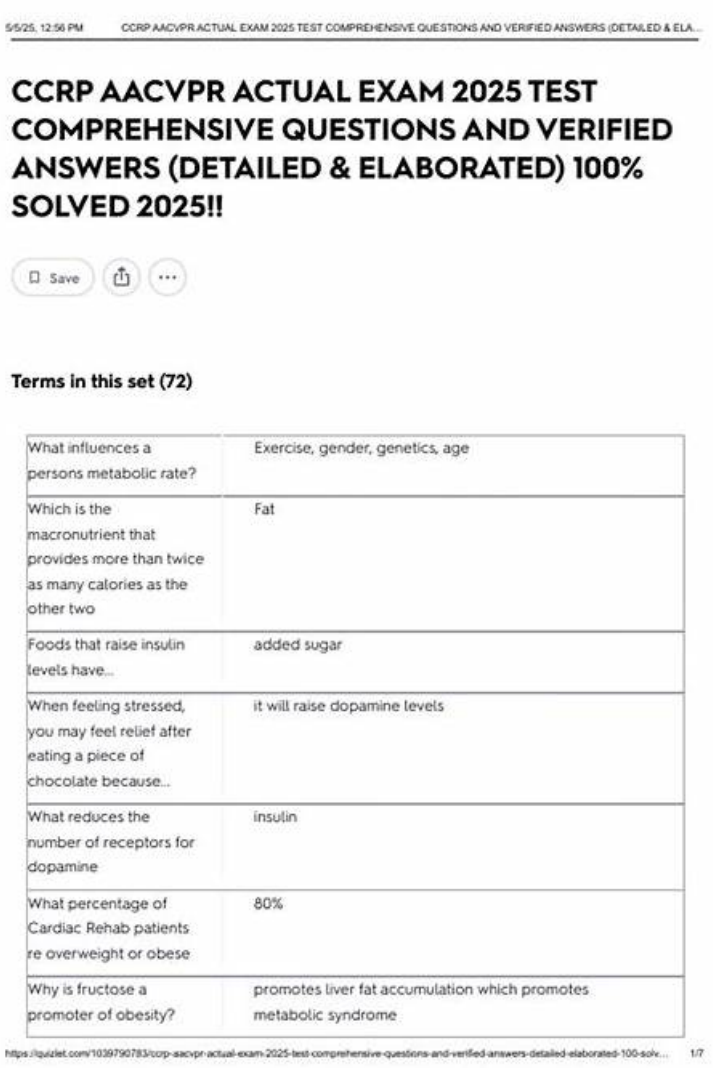

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**Terms in this set (72)**

| | |
|---|---|
| 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 (Q23-Q28):

**NEW QUESTION # 23**
A subject on a multi-drug regimen could not tolerate a non-investigational drug. Can the investigational regimen continue?

- A. Only after sponsor and IRB approval
- B. Only after medical monitor approval
- C. Yes, per protocol
- D. Only for a short time, then change to placebo

**Answer: A**

Explanation:
* ICH E6(R2) 4.5.1:Investigators must follow the protocol approved by the IRB/IEC.
* Any modification that is not pre-specified must be approved by sponsor and IRB before continuing.
Only deviations eliminating immediate hazard can be done without prior approval; in this case, continuation requires sponsor + IRB agreement.
References:ICH E6(R2) §4.5.1.

**NEW QUESTION # 24**
In a Phase III cardiovascular trial, who is responsible for ongoing clinical trial safety evaluation?

- A. FDA
- B. IRB/IEC
- C. Sponsor
- D. Pharmacist

**Answer: C**

Explanation:
* ICH E6(R2) 5.16:Sponsors must implement ongoing safety evaluation, including expedited and periodic reporting.FDA and IRB review but do not conduct active monitoring.
References:ICH E6(R2), §5.16.

**NEW QUESTION # 25**
A subject was instructed to do a glucose check 4 times a day for 10 days using an investigational glucose meter. The meter requires one new glucose test strip for each test. The subject received the meter along with
45 glucose test strips. How many unused test strips should the subject have after the 10 days?

- A. 0
- B. 1
- C. 2
- D. 3

**Answer: A**

Explanation:
This is adrug/device accountability calculation question, testing compliance with investigational product tracking.
* The subject was instructed to perform4 glucose checks per day.
* Over10 days, that equals40 tests (4 × 10 = 40).
* Each test requires1 strip, so40 strips used.
* Subject was given45 strips, leaving5 unusedafter 10 days.
Investigators are responsible for maintaining accurate device/product accountability.
* ICH E6(R2) 4.6.3:"The investigator/institution should maintain records of the product's delivery to the trial site, the inventory, the use by each subject, and the return to the sponsor or alternative disposition."
* This ensures monitoring can confirm that product/device use aligns with the protocol and subject adherence.
Thus, the correct answer isB (5 unused test strips).
References:
ICH E6(R2), §4.6.3 (Investigational product accountability).

**NEW QUESTION # 26**
In accordance with the ICH GCP Guideline, who is responsible for the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the case report forms and in all required reports?

- A. The clinical investigator
- B. The contract research organization monitor
- C. The quality control specialist
- D. The IRB/IEC coordinator

**Answer: A**

Explanation:
The investigator holds ultimate responsibility for all data reported.
* ICH E6(R2) 4.9.1:"The investigator is responsible for the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor on the CRFs and all required reports."
* Monitors (D) verify data accuracy but are not responsible for data quality. Quality specialists (B) and IRB staff (C) have no role in data entry.
Correct answer:A (The clinical investigator).
References:
ICH E6(R2), §4.9.1.

**NEW QUESTION # 27**
When can an IRB/IEC review a study using expedited review?

- A. For initial review of a study using specimens with identifiers
- B. For protocol changes involving more than minimal risk
- C. For minor changes to previously approved protocol
- D. For initial review of Phase III IND protocol

**Answer: C**

Explanation:
* 21 CFR 56.110(b):IRBs may use expedited review forminor changesin previously approved research.
* Expedited review cannot be used for initial reviews of high-risk protocols or major modifications.
Correct answer isD.
References:21 CFR 56.110(b).

**NEW QUESTION # 28**
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