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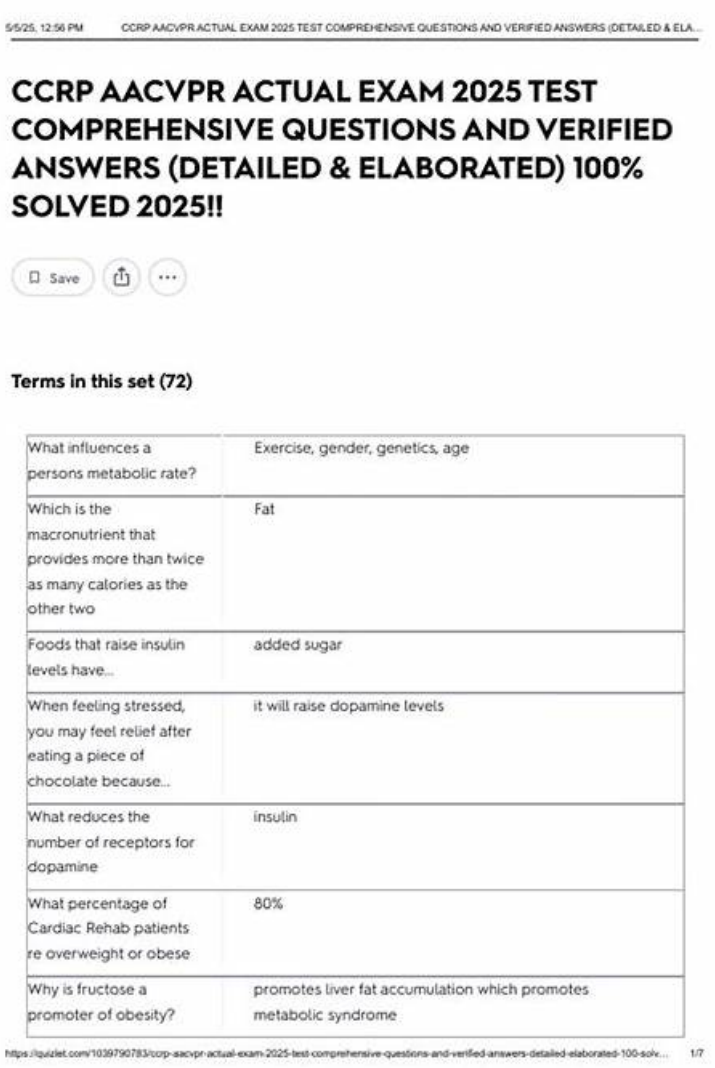

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What influences a persons metabolic rate?	Exercise, gender, genetics, age
Which is the macronutrient that provides more than twice as many calories as the other two	Fat
Foods that raise insulin levels have...	added sugar
When feeling stressed, you 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 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.
Topic 2	• 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.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q12-Q17):

NEW QUESTION # 12
In a completed multi-site Phase I drug study using remote EDC, who ensures the system complies with accuracy and reliability requirements?

- A. Sponsor
- B. Institution
- C. Investigator
- D. Regulatory authority

Answer: A

Explanation:
* ICH E6(R2) 5.5.3:Sponsors are responsible for validating computerized systems used in trials.
Investigators ensure proper data entry, but system compliance lies with sponsor.
References:ICH E6(R2), §5.5.3.

NEW QUESTION # 13
A monitor is conducting a site closeout visit. The study site kept electronic medical records and source documents in a system verified to be 21 CFR Part 11 compliant. The monitor reviewed all electronic documents by logging into the system with a unique login ID and password. In addition to the essential document file, which of the following sets of documents should be provided to the monitor during the study closeout visit?

- A. Informed consent documents and printouts of electronic source documents
- B. Printouts of electronic source documents and the remaining investigational product
- C. A copy of the final report for the IRB and investigational product shipment records
- D. Informed consent documents and investigational product documentation

Answer: D

Explanation:
During study closeout, the monitor verifies subject protection, protocol compliance, and investigational product accountability.
* ICH E6(R2) 8.1 & 8.4:Lists essential documents to be verified at closeout, including signed informed consent forms and investigational product accountability records.
* 21 CFR Part 11:Ensures electronic records are valid, so printed copies are not always necessary unless required for auditing.
Thus, the critical items for monitor review at closeout areinformed consent forms(to confirm subject protection) andinvestigational product documentation(to confirm reconciliation and disposition).
Correct answer:D.
References:
ICH E6(R2), §8.1, §8.4.

NEW QUESTION # 14
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 wouldNOTbe required to be filed at the research site?

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

Answer: D

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 destructionare 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 isD (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 # 15
In accordance with the ICH GCP Guideline, which of the following should the investigator refer to when a subject returns unused medication at the completion of a study?

- A. The Investigator's Brochure
- B. The investigational pharmacy's requirements
- C. The sponsor's written procedures
- D. The CRO/site agreements

Answer: C

Explanation:
Handling of investigational product (IP), including returns, is governed bysponsor's written procedures.
* ICH E6(R2) 4.6.3:"The investigator/institution should maintain records of the product's delivery, the inventory, the use by each subject, and the return to the sponsor or alternative disposition."
* ICH E6(R2) 5.13.3:"The sponsor should ensure that written procedures include instructions for... the return or alternative disposition of unused product(s)." The IB (A) describes pharmacology and safety, not IP logistics. CRO agreements (C) cover

contractual duties, not product return processes. Local pharmacy policies (D) may apply operationally but do not override sponsor-required procedures.
Thus, the correct answer isB (The sponsor's written procedures).
References:
ICH E6(R2), §4.6.3 (Investigator product accountability).
ICH E6(R2), §5.13.3 (Sponsor product return procedures).

NEW QUESTION # 16
When can the IRB/IEC require that additional information be given to subjects as part of informed consent?

- A. At any time, but only if the investigator agrees that the information is essential
- B. At any time, but only if the sponsor and investigator agree that the information is essential
- C. At any time, but only if the sponsor agrees that the information is essential
- D. At any time, at the discretion of the IRB/IEC

Answer: D

Explanation:
The IRB/IEC is empowered to protect subjects and ensure informed consent remains accurate, complete, and understandable.
* ICH E6(R2) 3.1.2:"The IRB/IEC should safeguard the rights, safety, and well-being of all trial subjects. Special attention should be paid... when considering the adequacy and completeness of the written information to be provided to the subjects."
* 21 CFR 56.109(b):"The IRB shall require that information given to subjects as part of informed consent is in accordance with §50.25.The IRB may require that information, in addition to that specifically mentioned in §50.25, be given to the subjects when in its judgment the information would meaningfully add to the protection of the rights and welfare of subjects." This confirms that the IRB/IEC has unilateral authority to request additional information at any time, regardless of sponsor or investigator agreement.
Thus, the correct answer isA (At any time, at the discretion of the IRB/IEC).
References:
ICH E6(R2), §3.1.2 (IRB responsibilities).
21 CFR 56.109(b) (IRB review of informed consent).

NEW QUESTION # 17
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