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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 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	<ul style="list-style-type: none"><li>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.</li></ul>

Topic 2	<ul style="list-style-type: none"> <li>• <b>Research Study Start-Up:</b> 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.</li> <li>• <b>Research Study Implementation:</b> 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.</li> </ul>
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## SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q88-Q93):

### NEW QUESTION # 88

Which of the following statements about the FDA's authority to inspect IRB/IEC records is correct?

- A. The FDA may inspect them at reasonable times, in a reasonable manner, and may take copies of IRB /IEC records
- B. The FDA may inspect them only if the IRB/IEC formally requests inspection
- C. The FDA does not have regulatory authority to inspect them
- D. The FDA may inspect them at reasonable times, in a reasonable manner, but may not take copies unless requested with an affidavit

**Answer: A**

Explanation:

The FDA has full regulatory authority to inspect IRB/IEC records.

\* 21 CFR 56.115(b): "The IRB shall permit representatives of the Food and Drug Administration to inspect and copy all records maintained... at reasonable times and in a reasonable manner." Thus, FDA may inspect and copy IRB/IEC records without requiring an affidavit or invitation. This ensures regulatory oversight and human subject protection.

Incorrect options:

- \* (A) limits authority incorrectly.
- \* (C) is false - FDA explicitly regulates IRBs.
- \* (D) is false - FDA does not need IRB invitation.

Correct answer: B.

References:

21 CFR 56.115(b).

### NEW QUESTION # 89

A clinical investigator is planning to conduct a quality of life medical device study in the United States. The study has been designed to comply with the approved indication for use of the device. In this situation, who must approve the investigator's proposed patient recruitment materials?

- **A. An IRB/IEC**
- B. The Office for Human Research Protections (OHRP)
- C. The FDA
- D. A scientific review board

**Answer: A**

Explanation:

Recruitment materials must be reviewed to protect subjects from misleading or coercive messaging.

\* 21 CFR 56.111(a)(3):IRBs must ensure equitable subject selection.

\* ICH E6(R2) 3.1.2:IRBs safeguard rights, safety, and well-being, including review of recruitment strategies.

FDA and OHRP do not approve recruitment materials; responsibility lies with IRB/IEC.

References:21 CFR 56.111(a)(3); ICH E6(R2) §3.1.2.

#### **NEW QUESTION # 90**

A Phase I clinical trial is initiating. Who is responsible for ensuring that site staff are adequately informed about trial duties?

- **A. Clinical investigator**
- B. IRB/IEC
- C. Program manager
- D. Sponsor

**Answer: A**

Explanation:

\* ICH E6(R2) 4.2.4:"The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, investigational product, and trial-related duties."This responsibility cannot be delegated to sponsor or IRB.

References:ICH E6(R2), §4.2.4.

#### **NEW QUESTION # 91**

A clinical investigator wants to publish a subject's unique results. The consent form did not mention publication. What is required?

- A. IRB chair approval
- B. Approval from monitor
- **C. Consent from subject**
- D. Nothing further

**Answer: C**

Explanation:

\* ICH E6(R2) 4.8.10(n):Consent must include explanation about confidentiality and possible publication.

\* If not included, specific subject consent must be obtained before publishing identifiable results.

Thus, subject's explicit permission is required.

References:ICH E6(R2) §4.8.10(n).

#### **NEW QUESTION # 92**

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: C**

Explanation:

This is a drug/device accountability calculation question, testing compliance with investigational product tracking.

- \* The subject was instructed to perform 4 glucose checks per day.
- \* Over 10 days, that equals 40 tests ( $4 \times 10 = 40$ ).
- \* Each test requires 1 strip, so 40 strips used.
- \* Subject was given 45 strips, leaving 5 unused after 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 is B (5 unused test strips).

## References:

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

### NEW QUESTION # 93

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