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5/5/25, 12:56 PM CCRP AACVPR ACTUAL EXAM 2025 TEST COMPREHENSIVE QUESTIONS AND VERIFIED ANSWERS (DETAILED & ELA...

## 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 <a href="http://clinicaltrials.gov">clinicaltrials.gov</a>. 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 (Q45-Q50):

#### NEW QUESTION # 45

A nonrandomized study of 30 subjects entitled "A study to evaluate the effectiveness of and to determine the common short-term side effects associated with the drug 'PainStop' for the treatment of subjects with chronic arthritis" is an example of a:

- A. Phase II
- B. Phase III
- C. Phase I
- D. Phase IV

**Answer: A**

Explanation:

Phase classification is based on study objectives, not just subject numbers.

\* Phase I: Focuses on safety, pharmacokinetics, dose-ranging, usually in healthy volunteers or small patient groups.

\* Phase II: Evaluates effectiveness in patients with the condition and monitors common short-term side effects.

\* Phase III: Confirms effectiveness in larger populations, compares to standard therapy, gathers more safety data.

\* Phase IV: Post-marketing studies exploring new indications, long-term safety, or special populations.

The given study aims to evaluate effectiveness and common short-term side effects in 30 arthritis patients, which clearly aligns with Phase II objectives. It is not exploratory safety (Phase I), not confirmatory comparative (Phase III), nor post-marketing (Phase IV).

Thus, the correct answer is B (Phase II).

References:

FDA Guidance: The IND Application - §312.21 (Phases of an investigation).

ICH E8(R1), General Considerations for Clinical Studies.

#### NEW QUESTION # 46

Upon completion of a study, the investigator should do which of the following?

- A. Provide the IRB/IEC a final report, but only if the study has a positive outcome
- B. Compile site data, publish the study results, and submit the publication to the IRB/IEC as the final report
- **C. As soon as possible, provide the IRB/IEC with a final report that summarizes the trial's outcome**
- D. Ensure that all payments from sponsor have been received

**Answer: C**

Explanation:

Investigators must formally close out a trial with the IRB/IEC.

\* ICH E6(R2) 4.13.2: "Upon completion of the trial, the investigator/institution should provide the IRB/IEC with a summary of the trial's outcome."

\* 21 CFR 312.66: Reinforces investigator's duty to keep IRB informed throughout study lifecycle.

This applies regardless of whether outcomes were positive, negative, or inconclusive. IRBs are not concerned with sponsor payments (B) or publications (D).

Thus, the correct answer is A (Provide final report to IRB/IEC).

References:

ICH E6(R2), §4.13.2 (Final reporting requirement).

#### NEW QUESTION # 47

Which of the following adverse events occurring during a study of an investigational new drug would require the sponsor to notify the FDA as soon as possible but in no case later than seven calendar days after the initial receipt of the information?

- **A. Death as a result of arrhythmias (irregular heart rhythm), not mentioned in the investigator's brochure and thought to be related to the use of the drug**
- B. Aplastic anemia requiring hospitalization, mentioned in the investigator's brochure
- C. An infection not related to the investigational drug requiring hospitalization for antibiotic therapy
- D. Death due to disease progression, mentioned in the investigator's brochure

**Answer: A**

Explanation:

Sponsors must report serious, unexpected, and suspected adverse reactions (SUSARs) to the FDA.

\* 21 CFR 312.32(c)(2): "Any adverse experience associated with the use of the drug that is both serious and unexpected shall be reported...as soon as possible but no later than 7 calendar days after the sponsor's initial receipt of the information, if it is fatal or life-threatening."

\* ICH E2A 4.2: Requires expedited reporting of life-threatening or fatal SUSARs within 7 days.

Among the options, only (C) - death from arrhythmias not previously identified in the Investigator's Brochure and suspected to be drug-related - meets the definition of a SUSAR requiring 7-day expedited reporting. Events already listed in the IB (A, D) or unrelated to the drug (B) do not trigger expedited reporting.

Thus, the correct answer is C.

References:

21 CFR 312.32(c)(2) (Expedited safety reporting).

ICH E2A, §4.2 (Expedited reporting of fatal/life-threatening adverse events).

#### NEW QUESTION # 48

According to the CFR, which of the following is a complete and accurate list of the signatures required on the short form consent document?

- A. The subject or else the subject's legally authorized representative; the investigator or else the investigator's designee
- **B. The subject or else the subject's legally authorized representative; the witness**
- C. The subject or else the subject's legally authorized representative
- D. The subject or else the subject's legally authorized representative; the investigator or else the investigator's designee; the witness

**Answer: B**

Explanation:

The short form consent process is permitted when the subject is presented with a brief written statement that they were informed of the study, supplemented by an oral presentation.

\* 21 CFR 50.27(b)(2): Requires the short form to be signed by the subject (or legally authorized representative) and a witness.

\* The witness ensures that oral consent was properly conveyed and understood.

\* The person obtaining consent must sign a separate written summary, but not the short form itself.

Thus, the accurate answer is A: subject (or LAR) + witness.

References:

21 CFR 50.27(b)(2).

#### NEW QUESTION # 49

A company's CEO wants to commercially promote a device under an IDE study. This plan:

- A. Requires IDE approval
- B. Requires a large advertising budget
- C. **Would violate FDA regulations**
- D. Requires IRB/IEC approval

**Answer: C**

Explanation:

\* 21 CFR 812.7: Prohibits promotion of investigational devices or claiming safety/effectiveness until FDA approval is granted.

\* Investigational devices may only be used in clinical trials, not marketed.

Thus, promotion during an IDE study is an FDA violation.

References: 21 CFR 812.7.

#### NEW QUESTION # 50

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