

# New CCRP Test Notes | New APP CCRP Simulations

## CCRP AACVPR Test with Answers. 2023

- 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
- What reduces the rate of carbohydrate absorption thus reducing insulin response -  
✓ Fiber
- Depression among cardiac patients has been associated with -  
✓ higher risk of mortality
- When a patient scores in the depressed range on a screening, which action should be taken -  
✓ results to be discussed with patient and health care provider
- if a patient dense feeling of sadness they... -  
✓ may have non-dysphoric depression
- depression is relevant to CR because -  
✓ depression reduces recovery from exercise due to fatigue and low energy
- the relationship between anger and hostility is.. -  
✓ anger is the emotion, hostility is the thought
- social isolation is defined by -

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PassCollection CCRP Web-Based Practice Test: For the Certified Clinical Research Professional (CCRP) (CCRP) web-based practice exam no special software installation is required. Because it is a browser-based SOCRA CCRP practice test. The web-based Certified Clinical Research Professional (CCRP) (CCRP) practice exam works on all operating systems like Mac, Linux, iOS, Android, and Windows. In the same way, IE, Firefox, Opera and Safari, and all the major browsers support the web-based CCRP practice test.

## SOCRA CCRP Exam Syllabus Topics:

Topic	Details

Topic 1	<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>
Topic 2	<ul style="list-style-type: none"> <li>• <b>Research Study Closure:</b> 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>

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### SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q20-Q25):

#### NEW QUESTION # 20

A sponsor-investigator implemented a protocol deviation in a device trial to eliminate an immediate hazard. Before applying this change to all subjects, what must occur?

- A. Obtain IRB/IEC approval
- B. Train sub-investigators
- C. Document change in study file
- D. Inform all subjects

**Answer: A**

Explanation:

\* 21 CFR 812.35(a)(2): Allows deviation without prior approval only to eliminate immediate hazards.

\* Before applying broadly, IRB approval must be obtained.

References: 21 CFR 812.35(a)(2).

#### NEW QUESTION # 21

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 FDA
- C. The Office for Human Research Protections (OHRP)
- 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 # 22

The study coordinator for a new Phase III vaccine study is preparing documents for IRB/IEC submission.

According to the ICH GCP Guidelines, which of the following documents should be included in the submission?

- **A. Recruitment materials**
- B. Case report forms
- C. The investigators' CVs
- D. Local lab normal ranges

**Answer: A**

Explanation:

IRBs/IECs are responsible for ensuring that subject recruitment is ethical and not coercive.

\* ICH E6(R2) 3.1.2:The IRB/IEC safeguards subjects by reviewing recruitment procedures and materials.

\* 21 CFR 56.111(a)(3):Requires equitable subject selection, which extends to advertisements and recruitment.

\* FDA Guidance on Recruiting Study Subjects (1998):States that "advertisements and recruitment materials must be reviewed and approved by the IRB prior to use." While CVs (D) and lab ranges (A) are essential documents for study feasibility and quality, they are not mandatory for IRB approval package. CRFs (B) are sponsor tools for data collection, not subject-facing, and thus not reviewed by IRBs.

Correct answer:C (Recruitment materials).

References:

ICH E6(R2), §3.1.2.

FDA Recruitment Guidance, 1998.

### NEW QUESTION # 23

The sponsor of a multi-institutional clinical trial provided a site with information regarding a newly identified unanticipated adverse event attributed to study drug administration. The site's investigator has a subject actively receiving this study drug. Which of the following is the site investigator's responsibility to the subject?

- A. To submit this safety update to the regulatory authority
- B. To discontinue the subject's study drug
- C. To give the subject's contact information to the sponsor in order to allow the sponsor to contact the subject
- **D. To provide the subject with information regarding the significant new findings**

**Answer: D**

Explanation:

Investigators are obligated to inform subjects of new information that may affect their willingness to continue.

\* ICH E6(R2) 4.8.2:"If new information becomes available that may be relevant to a subject's willingness to continue participation, the informed consent document should be revised, and the subject should be informed in a timely manner."

\* 21 CFR 50.25(b)(5):Consent must include a statement that "significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided." Thus, the investigator must communicate new risk information to the subject.

Discontinuation (A) may not be warranted unless medically indicated. Reporting to FDA (B) is the sponsor's role. Sharing subject contact with sponsor (D) would violate confidentiality.



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