

CCRP Reliable Test Dumps, Valid CCRP Exam Pattern

CCRP AACVPR EXAM LATEST ACTUAL EXAM TEST BANK 520+ QUESTIONS AND CORRECT DETAILED ANSWERS|AGRADE

What insulin dose adjustment type would be most effective for preventing hypoglycemia during moderate exercise - ANSWER- **Reduction of rapid acting insulin dose 2-3 hours prior to exercise**
-A temporary basal rate decrease 45-60 minutes prior to exercise

Which medications place a patient at risk for hypoglycemia - ANSWER- **Insulin (Lantus, Novolog) and Sulfonylureas (Glipizide, glimepiride)**

How long can significant exercise induced enhancement of glucose uptake from muscle last - ANSWER- **24-48 hours**

Recommended calories from carbs, protein, and fats to better manage diabetes - ANSWER- **~40% calories from fiber-rich carbs**
~30% calories from lean protein
~30% calories from healthy fats

Cardiac effects of nicotine - ANSWER- **modest increase in HR, BP and myocardial contractility**

The stethoscope for smoking is.. - ANSWER- **a carbon monoxide analyzer that measures the amount of CO the patient exhales**

Carbon monoxide - ANSWER- **binds more readily than oxygen to hemoglobin resulting in relative hypoxia**

The question regarding Time to First Cigarette is primarily used to.. - ANSWER- **determine the level of dependence**

The gold standard for improving smoking quit rates is - ANSWER- **pharmacotherapy which doubles quit rates**

Smoking cessation in patients with CVD reduces the risk of death by - ANSWER- **36%**

In order to have the greatest benefit of lowering risk of MU or death, which should replace saturated fat in diet - ANSWER- **polyunsaturated fat**

What diet is recommended by AHA/ACC? - ANSWER- **DASH diet**

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SOCRA CCRP Exam Syllabus Topics:

Topic	Details
Topic 1	<ul style="list-style-type: none">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	<ul style="list-style-type: none">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 (Q44-Q49):

NEW QUESTION # 44

When can an IRB/IEC review a study using expedited review?

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

Answer: B

Explanation:

* 21 CFR 56.110(b): IRBs may use expedited review for minor changes in previously approved research.

* Expedited review cannot be used for initial reviews of high-risk protocols or major modifications.

Correct answer is D.

References: 21 CFR 56.110(b).

NEW QUESTION # 45

During an audit of a sponsor, the following documents and activities were reviewed: the protocol, applicable regulatory requirements, and compliance with Good Clinical Practice (GCP). What additional documents must be reviewed during the sponsor audit?

- **A. Audit reports**
- B. Financial reports
- C. Personnel records
- D. Standard Operating Procedures (SOPs)

Answer: A

Explanation:

Sponsor audits ensure systems comply with GCP.

* ICH E6(R2) 5.19.3: "The sponsor's auditing procedures should include a review of quality assurance audits and audit reports."

* Audit reports document findings from independent evaluations and are essential for ensuring compliance.

SOPs (A) are reviewed during audits but are not mandated as standalone "audit review documents." Personnel files (B) and financial reports (C) are not required under GCP auditing provisions.

Correct answer: D (Audit reports).

References:

ICH E6(R2), §5.19.3.

NEW QUESTION # 46

A study will enroll 420 subjects over 3.5 years. What is expected average monthly accrual?

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

Answer: C

Explanation:

$420 \text{ subjects} \div 42 \text{ months (3.5 years)} = 10 \text{ subjects/month}$.

However, "expected average" often rounds up to next whole number, ensuring enrollment goals are met. Thus, 11/month is correct.

This calculation is important for feasibility assessments and protocol planning.

References: Standard feasibility calculations (ICH E6(R2) §5.6).

NEW QUESTION # 47

A Phase I study of a new blood pressure medication has been submitted for initial approval to an IRB/IEC. In accordance with the CFR, the IRB/IEC must consider which of the following criteria when determining whether to approve the study?

- A. The equitability of the selection of subjects
- B. The funding source for the trial
- C. The educational background of the study team
- D. The availability of the patient population

Answer: A

Explanation:

When reviewing protocols, IRBs/IECs are primarily responsible for safeguarding human subjects by evaluating risks, benefits, and fairness in subject selection.

* 21 CFR 56.111(a)(3): "In making its determination the IRB shall determine that... selection of subjects is equitable."

* 45 CFR 46.111(a)(3): Repeats this requirement, emphasizing fairness across gender, race, age, and socioeconomic status.

Other options:

* Patient population availability (A) is a feasibility issue, addressed by investigators and sponsors, not IRBs.

* Education of the study team (C) is confirmed by the sponsor and investigator, not IRB.

* Funding sources (D) may raise conflict of interest concerns, but they are not IRB approval criteria per federal regulations.

Thus, IRBs focus on justice and fairness in subject selection as part of the Belmont Report principles.

References:

21 CFR 56.111(a)(3).

Belmont Report (Justice principle).

NEW QUESTION # 48

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. Train sub-investigators
- B. Inform all subjects
- C. Document change in study file

- D. Obtain IRB/IEC approval

Answer: D

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 # 49

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