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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 are overweight or obese	80%
Why is fructose a promoter of obesity?	promotes liver fat accumulation which promotes metabolic syndrome

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Passing an Certified Clinical Research Professional (CCRP) exam on the first attempt can be stressful, but SOCRA CCRP exam questions can help manage stress and allow you to perform at your best. We at ExamDumpsVCE give you the techniques and resources to make sure you get the most out of your exam study. We provide preparation material for the Certified Clinical Research Professional (CCRP) exam that will guide you when you sit to study for it. CCRP updated questions give you enough confidence to sit for the SOCRA exam.

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.
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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q18-Q23):

NEW QUESTION # 18

In accordance with the ICH GCP Guideline, when a sponsor transfers trial-related duties and functions to a contract research organization (CRO), who is ultimately responsible for the quality and integrity of the trial data?

- A. The investigator
- B. The IRB/IEC
- C. The CRO
- D. The sponsor

Answer: D

Explanation:

Outsourcing does not shift ultimate responsibility away from the sponsor. Exact extract:

* ICH E6(R2) 5.2.1: "A sponsor may transfer any or all of the sponsor's trial-related duties... to a CRO, but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor." Hence, D is correct.

References:

ICH E6(R2) Good Clinical Practice, §5.2.1 (Sponsor/CRO).=====

NEW QUESTION # 19

An IND application must contain all EXCEPT:

- A. Financial disclosure information
- B. A cover sheet
- C. Chemistry, manufacturing, and control information
- D. Investigator's brochure

Answer: A

Explanation:

- * 21 CFR 312.23(a):Requires cover sheet, CMC information, and IB.
- * Financial disclosure is required separately under 21 CFR 54, not part of IND content.

References:21 CFR 312.23(a); 21 CFR 54.

NEW QUESTION # 20

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

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

Answer: B

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 # 21

After the completion of a Phase II IND study closeout monitoring visit, which of the following parties is responsible for maintaining the closeout monitoring report?

- A. The investigator
- B. The study coordinator
- C. The IRB/IEC
- **D. The sponsor**

Answer: D

Explanation:

Monitoring reports are sponsor-controlled documents.

- * ICH E6(R2) 5.18.6:"The monitor should submit a written report to the sponsor after each trial-site visit... The sponsor should review and follow up on the monitoring report."

- * ICH E6(R2) 8.1 & 8.2.22:Monitoring visit reports are essential documents maintained by the sponsor.

Investigators are not required to retain monitoring reports; they maintain site regulatory binders and subject records. The study coordinator assists investigators, but does not hold sponsor-owned reports. IRBs also do not receive sponsor monitoring reports. Thus, the correct answer is B (The sponsor).

References:

ICH E6(R2), §5.18.6 (Monitoring reports).

ICH E6(R2), §8.2.22 (Essential documents: monitoring visit reports).

NEW QUESTION # 22

A study subject in a double-blinded, placebo-controlled Phase III study experienced a serious adverse event that could be related to the study drug. The clinical investigator is out of town, and the sub-investigator needs to break the blind. Where can the sub-investigator find a description of the unblinding procedure?

- A. The Investigator's Brochure
- B. The case report form
- **C. The study protocol**
- D. The informed consent form

Answer: C

Explanation:

Unblinding procedures are a protocol-level responsibility because they involve trial design, safety management, and subject

protection.

* ICH E6(R2) 6.0 (Protocol and amendments):Requires the protocol to specify "the treatment(s) and treatment periods, procedures for randomization and blinding, and procedures for breaking codes."

* ICH E6(R2) 4.7: "The investigator should follow the trial's randomization procedure, if any, and should ensure that the code is broken only in accordance with the protocol." The informed consent (A) explains risks and rights but does not include operational unblinding procedures.

The Investigator's Brochure (B) summarizes preclinical/clinical data but does not dictate site-specific trial management. The CRF (D) is for data capture and has no procedural detail.

Therefore, the correct answer is C (The study protocol), as it outlines unblinding steps and documentation requirements.

References:

ICH E6(R2), §6.0 (Protocol content).

ICH E6(R2), §4.7 (Randomization and unblinding).

NEW QUESTION # 23

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