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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">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 (Q126-Q131):

NEW QUESTION # 126

In accordance with the CFR, the sponsor (who is not a sponsor-investigator) is responsible for which of the following?

- A. Maintaining case histories that record all observations and other data pertinent to the investigation
- B. Overseeing the administration of the investigational drug to the subjects
- C. Ensuring that the FDA and all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug
- D. Submitting progress reports to the reviewing IRB/IEC

Answer: C

Explanation:

Sponsors are responsible for distributing safety updates across all investigators and the FDA.

* 21 CFR 312.55(b): "The sponsor shall promptly notify all participating investigators, and the FDA, of new significant adverse effects or risks with respect to the drug." Other responsibilities fall elsewhere:

* Case histories (C) are maintained by investigators (21 CFR 312.62(b)).

* Progress reports to IRBs (D) are the investigator's duty (21 CFR 312.66).

* Administration of investigational drug (A) is managed by the investigator at site level.

Thus, the correct answer is B (Ensuring FDA and investigators are promptly informed).

References:

21 CFR 312.55(b) (Sponsor notification requirements).

NEW QUESTION # 127

An investigator reports a serious adverse event suspected to be drug-related. By CFR, the sponsor must notify FDA no later than:

- A. 1 day
- B. 10 days
- C. 15 days
- D. 7 days

Answer: D

Explanation:

* 21 CFR 312.32(c)(2): Life-threatening or fatal unexpected adverse events must be reported within 7 calendar days. Other serious unexpected events are reported within 15 days.

References: 21 CFR 312.32(c)(2).

NEW QUESTION # 128

Which of the following statements about the investigator's brochure is correct?

- A. It includes financial disclosure information from investigators
- B. It provides documents that permit the evaluation of the conduct of the study and the quality of the data
- C. It consists of the instructions for the investigator to conduct the study
- **D. It contains a summary of the pharmacological and toxicological effects of the drug in animals, and to the extent known, in humans**

Answer: D

Explanation:

The Investigator's Brochure (IB) is a critical regulatory document designed to provide investigators with comprehensive knowledge about an investigational product.

* ICH E6(R2) 7.1: Defines the IB as "a compilation of the clinical and nonclinical data on the investigational product(s) that are relevant to the study of the product(s) in human subjects."

* ICH E6(R2) 7.2.2: Specifies the IB should contain a summary of pharmacological, toxicological, pharmacokinetic, and metabolic studies in animals, as well as results from previous human experience.

* The purpose is to allow investigators to make risk-benefit assessments, support protocol design, and ensure subject safety.

Incorrect options:

* A (instructions to conduct study) describes the protocol, not the IB.

* C (financial disclosures) are required under 21 CFR 54, not part of the IB.

* D refers to trial master file/essential documents, not the IB.

Therefore, the IB's defining function is to provide a scientific summary of preclinical and clinical data supporting safe human use.

References:

ICH E6(R2), §7.1, §7.2.2.

NEW QUESTION # 129

During an audit for a Phase II IND study, the auditor identified unreported serious protocol deviations. Which party must take prompt action to ensure compliance?

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

Answer: A

Explanation:

The sponsor holds ultimate responsibility for trial oversight and compliance.

* ICH E6(R2) 5.20.1: If noncompliance is discovered, the sponsor must "take prompt action to secure compliance" and, if necessary, terminate participation of the investigator/institution.

* 21 CFR 312.56(b): Sponsors must ensure proper conduct and report investigators who fail to comply to the FDA and IRB.

While investigators commit to protocol adherence, once deviations are identified, the sponsor must act to safeguard subjects and trial validity.

References: ICH E6(R2) §5.20.1; 21 CFR 312.56(b).

NEW QUESTION # 130

Which of the following is one of the responsibilities of an investigator who is NOT a sponsor?

- A. Ensuring that all participating investigators are promptly informed of significant new adverse events
- B. Reporting serious adverse events to the applicable regulatory agency
- **C. Maintaining control of the investigational product**
- D. Ensuring proper monitoring of an investigation at all investigational sites

Answer: C

Explanation:

For non-sponsor investigators, responsibilities are limited to site-level conduct and product accountability.

* ICH E6(R2) 4.6.1: "Responsibility for investigational product(s) accountability at the trial site rests with the investigator/institution."

* 21 CFR 312.61: Requires the investigator to administer investigational drugs only to subjects under their supervision and maintain control.

Other responsibilities listed belong to sponsors:

* A: Reporting SAEs to FDA is a sponsor duty (investigators report to sponsor, not directly to FDA).

* B: Monitoring at all sites is a sponsor responsibility.

* C: Disseminating safety updates is a sponsor's role.

Correct answer: D (Maintaining control of IP).

References:

ICH E6(R2), §4.6.1.

21 CFR 312.61.

NEW QUESTION # 131

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