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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 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.
Topic 2	<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.

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q35-Q40):

NEW QUESTION # 35

In order to adequately monitor a clinical trial, the monitor must be familiar with each of the following, EXCEPT the:

- A. Requirements for storage of the investigational product
- B. Sponsor's SOPs
- C. IRB/IEC requirements for reporting to the regulatory authority
- D. Written information to be provided to the subjects

Answer: C

Explanation:

Monitors verify compliance with protocol, sponsor SOPs, GCP, and regulations.

* ICH E6(R2) 5.18.4: Outlines monitor responsibilities, including verifying informed consent, protocol compliance, investigational product accountability, and adherence to sponsor SOPs.

* Monitors must also be familiar with subject-facing documents (A) and storage requirements for investigational product (B).

However, IRB/IEC requirements for reporting to regulatory authorities are outside a monitor's scope.

That responsibility lies with investigators and IRBs under 21 CFR 56.108(b).

Thus, the correct answer is D.

References:

ICH E6(R2), §5.18.4.

21 CFR 56.108(b).

NEW QUESTION # 36

During the closeout visit, a monitor is completing the documentation of reconciliation of investigational product. All packaging, as well as the used and unused investigational product, are being returned to the sponsor for disposition. Which of the following documents would NOT be required to be filed at the research site?

- A. Records of investigational product shipment
- B. Investigational product accountability forms
- C. Investigational product inventory forms
- D. A certificate of investigational product destruction

Answer: D

Explanation:

Investigators must document the receipt, use, return, or alternative disposition of investigational product (IP).

* ICH E6(R2) 4.6.3: Requires investigators to maintain records of IP delivery, inventory, use by subjects, and return/disposition.

* ICH E6(R2) 8.2.14-8.2.16: Essential documents include shipment records, accountability logs, and inventory records.

However, certificates of destruction are generated and retained by the sponsor (or authorized destruction facility), not required at the site unless the destruction occurred there. In this scenario, all IP was returned to the sponsor, so no destruction certificate would exist at the site.

Thus, the correct answer is D (Certificate of destruction).

References:

ICH E6(R2), §4.6.3 (Investigator product accountability).

ICH E6(R2), §8.2.14-8.2.16 (Essential documents).

NEW QUESTION # 37

A coordinator for an ongoing industry-sponsored, multi-site Phase II clinical trial is taking an unexpected, long-term medical absence. The trial site retains coordinator services from an external source to support clinical trial activities. According to the ICH GCP Guideline, which of the following is responsible for implementing procedures to ensure the integrity of the clinical trial-related duties?

- A. The investigator/institution
- B. The IRB/IEC
- C. The sponsor
- D. The external source

Answer: A

Explanation:

The investigator/institution bears responsibility for site conduct, oversight of delegated tasks, and ensuring qualified, trained staff regardless of employment source. Exact extracts:

* ICH E6(R2) 4.1.1: "The investigator should be qualified... and have adequate resources to properly conduct the trial."

* ICH E6(R2) 4.1.5: "The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions."

* ICH E6(R2) 4.2.5: "The investigator may delegate... but retains responsibility for the conduct of the trial at the site." Therefore, the investigator/institution (B) must implement procedures and oversight to maintain integrity of trial duties.

References:

ICH E6(R2) Good Clinical Practice, §4.1.1; §4.1.5; §4.2.5 (Investigator responsibilities; delegation and oversight).=====

NEW QUESTION # 38

In accordance with the CFR and the ICH GCP Guideline, which of the following is directly responsible for submitting protocols and amendments to the IRB/IEC for review?

- A. The investigator
- B. The contract research organization
- C. The Food and Drug Administration
- D. The sponsor

Answer: A

Explanation:

The investigator bears direct responsibility for ensuring IRB/IEC review and approval before initiating a study or implementing any amendments.

* ICH E6(R2) 4.4.1: "Before initiating a trial, the investigator/institution should have written and dated approval/favorable opinion from the IRB/IEC for the trial protocol, written informed consent form, and any other written information to be provided to subjects."

* 21 CFR 312.66: "An investigator shall assure that an IRB that complies with the requirements... will be responsible for the initial and continuing review and approval of the proposed clinical study." While sponsors may provide protocol documents, the legal obligation to submit and maintain IRB/IEC approval rests with the investigator at each site. CROs act under sponsor delegation but cannot replace investigator accountability.

Thus, the correct answer is B (The investigator).

References:

ICH E6(R2), §4.4.1 (Investigator responsibilities).

21 CFR 312.66 (Investigator assurance of IRB oversight).

NEW QUESTION # 39

An investigator is working with a new sponsor to submit a cardiovascular trial to the IRB/IEC. In accordance with the ICH GCP Guidelines, which parties should sign the protocol to confirm agreement that the trial will be conducted as agreed?

- A. The sponsor and the IRB/IEC
- **B. The investigator/institution and the sponsor**
- C. The sponsor and the FDA
- D. The investigator/institution and the delegated site staff

Answer: B

Explanation:

The protocol signature page documents agreement between the sponsor and the investigator/institution to conduct the trial in compliance with ICH GCP, the protocol, and regulatory standards.

* ICH E6(R2) 8.2.2 (Signed protocol and amendments): Requires "the sponsor and investigator/institution to sign the protocol and amendments, confirming agreement."

* ICH E6(R2) 4.5.1: "The investigator should conduct the trial in compliance with the protocol agreed to by the sponsor and, if required, approved by the regulatory authority(ies) and by the IRB/IEC." The sponsor-investigator signatures ensure shared accountability for subject protection, data integrity, and adherence to trial methodology. Neither delegated staff (B) nor IRB/IEC (C) nor FDA (D) sign protocols.

These bodies approve or oversee, but do not formally enter into execution of the protocol.

Thus, the correct answer is A (The investigator/institution and the sponsor).

References:

ICH E6(R2), §8.2.2 (Signed protocol and amendments).

ICH E6(R2), §4.5.1 (Investigator compliance with protocol).

NEW QUESTION # 40

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