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SOCRA CCRP Exam Syllabus Topics:

Topic	Details
Topic 1	• 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	• 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 (Q37-Q42):

NEW QUESTION # 37
The reviewing IRB/IEC determined that a minimal risk sponsor-investigator study is exempt from IRB/IEC review. How often, if ever, is the sponsor-investigator required to submit a continuing review to the IRB/IEC?

- A. Every two years
- B. Exactly one time, at study closure
- C. Every year
- D. There is no such requirement

Answer: D

Explanation:
Minimal risk studiesmay qualify for exemption or expedited review under45 CFR 46.101(b).
* 45 CFR 46.109(f):"Unless an IRB determines otherwise, continuing review of research is not required for research eligible for expedited review and determined to involve no more than minimal risk."
* ICH E6(R2) 3.1.4:Requires IRB review for clinical trials, but exemptions exist for minimal risk studies.
Therefore, once exempted, there isno requirement for continuing review, unless specifically required by the IRB. Submission at closure is optional depending on institutional policy but not a federal requirement.
Thus, the correct answer isD (No such requirement).
References:
45 CFR 46.109(f) (Exempt and expedited reviews).

NEW QUESTION # 38
Which of the following is an adequate definition of quality assurance for the conduct of a clinical trial?

- A. The planned and systematic actions established to ensure that the trial is performed and the data are generated, documented, and reported in compliance with GCP and the applicable regulatory requirements
- B. The systematic plan to review, approve, and monitor biomedical and behavioral research involving human subjects
- C. The act of reviewing and approving the investigational protocol and informed consent document
- D. An official review by a regulatory authority of documents, facilities, records, and any other resources that are deemed to be related to the trial

Answer: A

Explanation:
Quality assurance (QA)is proactive and systematic, designed to prevent errors and ensure compliance.
* ICH E6(R2) 1.46:Defines QA as "all those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented, and reported in compliance with GCP and applicable regulatory requirements." Option A describes IRB responsibilities, Option C describesaudit, and Option D describes protocol approval processes. OnlyBaccurately matches the ICH definition of QA. QA is distinct fromquality control (QC), which is operational and focused on detection of issues during conduct.
Thus, the correct answer isB.
References:
ICH E6(R2), §1.46 (Definition of Quality Assurance).

NEW QUESTION # 39
An investigator received an updated investigator's brochure from the sponsor; the update did not include changes related to subject safety. Which of the following parties, if any, is the investigator required to notify?

- A. No notification is required

- B. The IRB/IEC
- C. The regulatory authority
- D. The Data Safety Monitoring Board (DSMB)

Answer: A

Explanation:
TheInvestigator's Brochure (IB)is updated by the sponsor to reflect new scientific or clinical information.
* ICH E6(R2) 7.3:"The sponsor should revise the IB as soon as new, significant information becomes available."
* ICH E6(R2) 4.1.5:Requires the investigator to ensure staff are informed, but there isno requirementto notify IRB/IEC unless subject safety, rights, or risk profile is affected.
Since this update containedno changes related to subject safety, the investigator is not obligated to notify IRB/IEC, DSMB, or regulators. The updated IB must simply be filed in theregulatory binderand implemented at the site.
Thus, the correct answer isD (No notification is required).
References:
ICH E6(R2), §7.3 (Updating the Investigator's Brochure).
ICH E6(R2), §4.1.5 (Investigator responsibilities for informing staff).

NEW QUESTION # 40
A sponsor received a report from an investigator regarding the investigator's use of an investigational device without having obtained informed consent. The sponsor must submit a copy of the report to the FDA within:

- A. 5 working days
- B. 1 day
- C. 30 working days
- D. 10 working days

Answer: A

Explanation:
Informed consent is a fundamental ethical requirement. If it is violated in a device trial, the FDA requires rapid reporting.
* 21 CFR 812.150(b)(5):States that a sponsor shall submit to FDA "any report of use of a device without obtaining informed consent, within5 working daysafter the sponsor first receives notice of such use."
* This expedited reporting ensures FDA oversight of serious violations and protection of human subjects.
Incorrect options:
* A (1 day) is overly strict and not codified.
* C (10 days) and D (30 days) are too delayed to meet regulatory intent of immediate oversight.
Thus, the correct timeline iswithin 5 working days.
References:
21 CFR 812.150(b)(5).

NEW QUESTION # 41
In a Phase III cardiovascular trial, who is responsible for ongoing clinical trial safety evaluation?

- A. Sponsor
- B. Pharmacist
- C. FDA
- D. IRB/IEC

Answer: A

Explanation:
* ICH E6(R2) 5.16:Sponsors must implement ongoing safety evaluation, including expedited and periodic reporting.FDA and IRB review but do not conduct active monitoring.
References:ICH E6(R2), §5.16.

NEW QUESTION # 42
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