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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.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q80-Q85):

NEW QUESTION # 80
In accordance with the ICH GCP Guideline, at what intervals should the on-site study monitoring be performed?

- A. At least weekly
- B. Once a year until study close-out
- C. In a timely manner before, during, and after the study
- D. Every 4-6 weeks until study close-out

Answer: C

Explanation:
Monitoring ensures trial integrity and subject safety.
* ICH E6(R2) 5.18.3:"The sponsor should ensure that the trials are adequately monitored. The determination of the extent and nature of monitoring should be based on considerations such as the objective, purpose, design, complexity, blinding, size, and endpoints of the trial."
* Monitoring must occurbefore (initiation visit), during (periodic), and after (closeout).
It is not limited to fixed weekly or monthly intervals (A, B) and not as infrequent as yearly (D). Instead, it is risk-adapted and flexible, but must cover all phases of the study.
Correct answer:C (Timely manner before, during, and after).
References:
ICH E6(R2), §5.18.3.

NEW QUESTION # 81
In accordance with ICH, which of the following is an acceptable protocol review frequency for an IRB?

- A. 36 months
- B. 6 months
- C. 24 months
- D. 12 months

Answer: D

Explanation:
IRBs must review protocols at least annually to ensure ongoing subject protection.
* 21 CFR 56.109(f):"An IRB shall conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year."
* ICH E6(R2) 3.1.4:"The IRB/IEC should conduct continuing review of each ongoing trial at intervals appropriate to the degree of risk, but at least once per year." This establishes12 monthsas the minimum required interval. More frequent reviews (e.g., 6 months) may occur for higher-risk studies, but longer intervals (24-36 months) are not permitted.
Correct answer:B (12 months).
References:
21 CFR 56.109(f).
ICH E6(R2), §3.1.4.

NEW QUESTION # 82
A subject has creatinine 1.6 mg/dL, slightly above eligibility (#1.5). Investigator believes this is normal for size. When can subject be enrolled?

- A. After investigator documents explanation in chart
- B. After monitor approves deviation
- C. After repeat test confirms 1.6
- D. After sponsor revises eligibility and IRB approves amendment

Answer: D

Explanation:
* ICH E6(R2) 4.5.1:"The investigator should conduct the trial in compliance with the protocol approved by IRB/IEC."
* Deviations must not occur unless to eliminate hazard. Eligibility criteria cannot be overridden by investigator opinion.
Thus, enrollment requires protocol amendment and IRB approval.
References:ICH E6(R2), §4.5.1.

NEW QUESTION # 83
Which document was created by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and summarizes the basic ethical principles and guidelines for the conduct of research involving human subjects?

- A. The Belmont Report
- B. The Nuremberg Code
- C. The ICH Guidelines
- D. The Declaration of Helsinki

Answer: A

Explanation:
TheBelmont Report (1979), issued by the U.S. National Commission, identifiesthree core ethical principles guiding human subject research:
* Respect for Persons(informed consent, autonomy, protection of vulnerable populations).
* Beneficence(maximize benefits, minimize harms).
* Justice(fairness in subject selection and treatment).
* TheNuremberg Code (1947)was developed post-WWII to prevent unethical experiments.
* TheDeclaration of Helsinki (1964, updated)is a World Medical Association document guiding international physician research ethics.
* TheICH Guidelines (1996)outline harmonized regulatory requirements for good clinical practice.
Only the Belmont Report fits the description of a U.S.-based, principle-driven framework for human research ethics.
Thus, the correct answer isD (The Belmont Report).
References:
The Belmont Report (1979), National Commission for the Protection of Human Subjects.
45 CFR 46 (Human Subject Protections).

NEW QUESTION # 84
According to ICH GCP, who besides the sponsor should approve the financial aspects of a clinical trial?

- A. Investigator/institution
- B. DSMB
- C. OHRP
- D. Regulatory authority

Answer: A

Explanation:
* ICH E6(R2) 5.6.1:"The sponsor should ensure agreement from the investigator/institution on the financial aspects of the trial."This ensures transparency in compensation, reimbursement, and budget.
References:ICH E6(R2) §5.6.1.

NEW QUESTION # 85
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