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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 (Q24-Q29):

NEW QUESTION # 24
In accordance with the ICH GCP Guideline, which of the following can an Independent Data Monitoring Committee provide?

- A. An initial review and approval of a trial
- B. The selection of qualified investigators
- C. Suggestions for a new trial design
- D. Recommendations to stop a trial

Answer: D

Explanation:
AnIndependent Data Monitoring Committee (IDMC or DSMB)is a group of independent experts established to review accumulating safety and efficacy data during a trial. Their main role is to ensure subject protection and trial integrity.
* ICH E6(R2) 5.5.1:"The sponsor may consider establishing anindependent data-monitoring committee (IDMC)to assess the progress of a clinical trial, including the safety data and the critical efficacy endpoints, and to recommend to the sponsor whether to continue, modify, or stop a trial." Thus, DSMBs/IDMCsdo not perform trial approvals (A),do not design trials (C), anddo not select investigators (D). Their authority is strictly advisory, providing recommendations to sponsors about safety and whether continuation of the study is ethically justified. The sponsor makes the final decision, but DSMB recommendations are highly influential.
Therefore, the correct answer isB (Recommendations to stop a trial).
References:
ICH E6(R2), §5.5.1 (Independent Data Monitoring Committees).

NEW QUESTION # 25
A subject enrolled in a drug clinical trial has withdrawn from the study. In accordance with ICH GCP, which of the following documents should be consulted to determine whether the participant should be replaced?

- A. The Investigator's Brochure
- B. The informed consent document
- C. The data safety monitoring plan
- D. The protocol

Answer: D

Explanation:
Theprotocolgoverns all trial conduct, including whether subjects should be replaced when they withdraw.
* ICH E6(R2) 6.0:The protocol must contain "detailed information on trial design, methodology, statistical considerations, and the organization of the trial."
* ICH E6(R2) 6.9.2:The section on "Subject withdrawal or discontinuation" specifies "whether and under what conditions subjects may be replaced." Other documents serve different functions: the DSM plan (A) manages safety oversight, the IB (C) summarizes product background, and the consent form (D) explains subject rights but does not guide study conduct. Only theprotocolprovides the operational answer regarding replacement.
Thus, the correct answer isB (The protocol).
References:
ICH E6(R2), §6.0 (Protocol content).
ICH E6(R2), §6.9.2 (Subject withdrawal/discontinuation).

NEW QUESTION # 26
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 Nuremberg Code
- B. The Belmont Report
- C. The ICH Guidelines
- D. The Declaration of Helsinki

Answer: B

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 # 27
A physician with 20 years of experience is planning to be the site investigator for a multi-center, Phase I oncology clinical trial. In accordance with the ICH GCP Guideline, which of the following documents should the physician provide to the sponsor and the IRB/IEC?

- A. A letter of recommendation from a fellow physician
- B. A copy of medical license
- C. Proof of citizenship
- D. A curriculum vitae

Answer: D

Explanation:
Investigators must provideevidence of qualificationsto conduct the study.
* ICH E6(R2) 4.1.1:"The investigator should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial."
* ICH E6(R2) 8.2.10:Essential documents include thecurriculum vitae (CV)or other documents evidencing investigator qualifications, submitted to both sponsor and IRB/IEC.
Proof of citizenship (A) and letters of recommendation (B) are irrelevant. A copy of a medical license (D) may be provided but isnot

specifically requiredby ICH. The CV is the universally required document.
Thus, the correct answer isC (Curriculum vitae).
References:
ICH E6(R2), §4.1.1 (Investigator qualifications).
ICH E6(R2), §8.2.10 (Essential documents: CV).

NEW QUESTION # 28
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. The IRB/IEC
- B. No notification is required
- C. The regulatory authority
- D. The Data Safety Monitoring Board (DSMB)

Answer: B

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 # 29
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