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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 (Q59-Q64):

NEW QUESTION # 59
An unconscious patient experiencing life-threatening cardiac arrhythmias has been admitted to an emergency room. No FDA-approved treatment is available, and no legal representative is present. The clinical investigator determined that the use of an investigational antiarrhythmic drug is required. In accordance with the CFR, who must certify the investigator's determination?

- A. The sponsor's medical monitor
- B. An independent physician
- C. The sponsor's study monitor
- D. A sub-investigator

Answer: B

Explanation:
This scenario falls underemergency use of investigational drugs without informed consent.
* 21 CFR 50.23(a):Allows waiver of informed consent if subject faces a life-threatening condition, available treatments are unproven, and immediate use is required.
* 21 CFR 50.23(a)(3):Requires that "the determination... be reviewed and concurred with by a physician who is not otherwise participating in the clinical investigation." Thus, anindependent physician(not part of the trial team) must certify the necessity of emergency investigational use.
Sponsors and monitors (C, D) are not authorized by regulation to make such determinations. Sub-investigators (A) lack independence and would be conflicted.
Correct answer:B (Independent physician).
References:
21 CFR 50.23(a)(3).

NEW QUESTION # 60
A study coordinator is preparing an IRB submission for a Phase II oncology study. Which document must be included?

- A. Recruitment materials
- B. Case report forms
- C. List of potential subjects
- D. Record storage plan

Answer: A

Explanation:
* ICH E6(R2) 3.1.2 & FDA Recruitment Guidance (1998):Recruitment materials must be reviewed by IRB to ensure no coercion or misleading claims.
* CRFs and storage plans are sponsor/site tools, not IRB-reviewed documents.
References:ICH E6(R2) §3.1.2; FDA Recruitment Guidance, 1998.

NEW QUESTION # 61
The study coordinator for a new Phase III vaccine study is preparing documents for IRB/IEC submission.
According to the ICH GCP Guidelines, which of the following documents should be included in the submission?

- A. Recruitment materials
- B. Local lab normal ranges

- C. Case report forms
- D. The investigators' CVs

Answer: A

Explanation:
IRBs/IECs are responsible for ensuring that subject recruitment is ethical and not coercive.
* ICH E6(R2) 3.1.2:The IRB/IEC safeguards subjects by reviewing recruitment procedures and materials.
* 21 CFR 56.111(a)(3):Requires equitable subject selection, which extends to advertisements and recruitment.
* FDA Guidance on Recruiting Study Subjects (1998):States that "advertisements and recruitment materials must be reviewed and approved by the IRB prior to use." While CVs (D) and lab ranges (A) are essential documents for study feasibility and quality, they are not mandatory for IRB approval package. CRFs (B) are sponsor tools for data collection, not subject-facing, and thus not reviewed by IRBs.
Correct answer:C (Recruitment materials).
References:
ICH E6(R2), §3.1.2.
FDA Recruitment Guidance, 1998.

NEW QUESTION # 62
According to 21 CFR Part 11, each electronic signature must be unique and:

- A. Transferable to family
- B. Identical to handwritten signature
- C. Reassignable after validation
- D. Cannot be reused or reassigned

Answer: D

Explanation:
* 21 CFR 11.100(a):Requires that electronic signatures be "unique to one individual and shall not be reused or reassigned to anyone else."
* This ensures accountability and audit trail integrity.
References:21 CFR 11.100(a).

NEW QUESTION # 63
Which of the following is one of the responsibilities of an investigator?

- A. Maintaining accurate and current case histories of study subjects
- B. Selecting qualified monitors on the basis of training, experience, and expertise
- C. Participating in the IRB/IEC voting process for approval of their protocol
- D. Updating the investigator brochure with new safety information

Answer: A

Explanation:
Investigators are required to maintain accurate subject records, often referred to ascase histories.
* 21 CFR 312.62(b):"An investigator shall prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation."
* ICH E6(R2) 4.9.0:Reinforces that investigators are responsible for recording, handling, and storing clinical trial data.
Incorrect options:
* B: Investigators may present protocols but cannot vote on IRB approval.
* C: Sponsor responsibility (ICH E6 §5.18).
* D: Sponsors are responsible for IB updates (ICH E6 §7.3.1).
Correct answer:A.
References:
21 CFR 312.62(b).
ICH E6(R2), §4.9.0.

NEW QUESTION # 64
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Just like the old saying goes, there is no royal road to success, and only those who do not dread the fatiguing climb of gaining its numinous summits. In a similar way, there is no smoothly paved road to the CCRP certification. You have to work on it and get started from now. If you want to gain the related certification, it is very necessary that you are bound to spend some time on carefully preparing for the CCRP Exam, including choosing the convenient and practical study materials, sticking to study and keep an optimistic attitude and so on.

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