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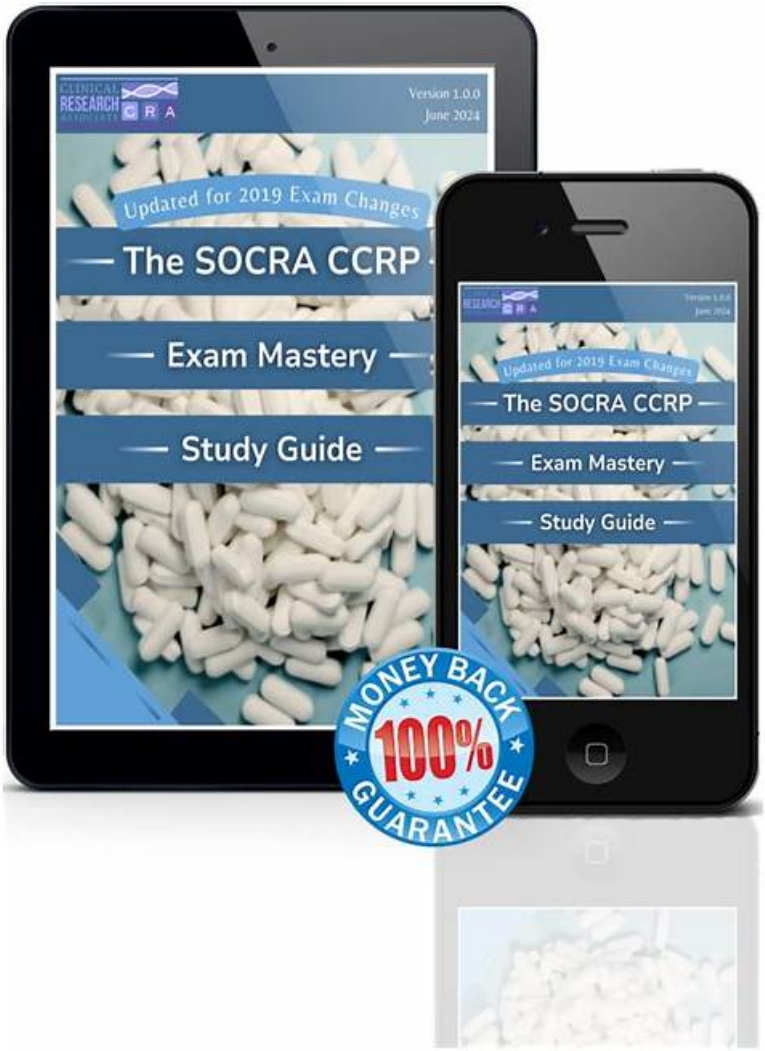

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SOCRA CCRP Exam Syllabus Topics:

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.

Exam CCRP Certification Cost & CCRP Real Exam Questions

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q88-Q93):

NEW QUESTION # 88
When can the IRB/IEC require that additional information be given to subjects as part of informed consent?

- A. At any time, but only if the sponsor and investigator agree that the information is essential
- B. At any time, at the discretion of the IRB/IEC
- C. At any time, but only if the sponsor agrees that the information is essential
- D. At any time, but only if the investigator agrees that the information is essential

Answer: B

Explanation:
The IRB/IEC is empowered to protect subjects and ensure informed consent remains accurate, complete, and understandable.
* ICH E6(R2) 3.1.2:"The IRB/IEC should safeguard the rights, safety, and well-being of all trial subjects. Special attention should be paid... when considering the adequacy and completeness of the written information to be provided to the subjects."
* 21 CFR 56.109(b):"The IRB shall require that information given to subjects as part of informed consent is in accordance with §50.25.The IRB may require that information, in addition to that specifically mentioned in §50.25, be given to the subjects when in its judgment the information would meaningfully add to the protection of the rights and welfare of subjects." This confirms that the IRB/IEC has unilateral authority to request additional information at any time, regardless of sponsor or investigator agreement.
Thus, the correct answer isA (At any time, at the discretion of the IRB/IEC).
References:
ICH E6(R2), §3.1.2 (IRB responsibilities).
21 CFR 56.109(b) (IRB review of informed consent).

NEW QUESTION # 89
A company's CEO wants to commercially promote a device under an IDE study. This plan:

- A. Requires IDE approval
- B. Would violate FDA regulations
- C. Requires IRB/IEC approval
- D. Requires a large advertising budget

Answer: B

Explanation:
* 21 CFR 812.7:Prohibits promotion of investigational devices or claiming safety/effectiveness until FDA approval is granted.
* Investigational devices may only be used in clinical trials, not marketed.
Thus, promotion during an IDE study is anFDA violation.
References:21 CFR 812.7.

NEW QUESTION # 90
An investigator reports a serious adverse event suspected to be drug-related. By CFR, the sponsor must notify FDA no later than:

- A. 1 day
- B. 7 days
- C. 15 days
- D. 10 days

Answer: B

Explanation:
* 21 CFR 312.32(c)(2):Life-threatening or fatal unexpected adverse events must be reported within7 calendar days.Other serious unexpected events are reported within 15 days.
References:21 CFR 312.32(c)(2).

NEW QUESTION # 91
Upon completion of a study, the investigator should do which of the following?

- A. As soon as possible, provide the IRB/IEC with a final report that summarizes the trial's outcome
- B. Ensure that all payments from sponsor have been received
- C. Provide the IRB/IEC a final report, but only if the study has a positive outcome
- D. Compile site data, publish the study results, and submit the publication to the IRB/IEC as the final report

Answer: A

Explanation:
Investigators must formally close out a trial with the IRB/IEC.
* ICH E6(R2) 4.13.2:"Upon completion of the trial, the investigator/institution should provide the IRB /IEC with a summary of the trial's outcome."
* 21 CFR 312.66:Reinforces investigator's duty to keep IRB informed throughout study lifecycle.
This applies regardless of whether outcomes were positive, negative, or inconclusive. IRBs are not concerned with sponsor payments (B) or publications (D).
Thus, the correct answer isA (Provide final report to IRB/IEC).
References:
ICH E6(R2), §4.13.2 (Final reporting requirement).

NEW QUESTION # 92
A clinical investigator is developing the assent procedure for the enrollment of children into a new pediatric clinical trial. The ages of the children are described in the IRB/IEC submission. A description of which of the following must also be included in the submission?

- A. The psychological status of the children
- B. The physiological status of the children
- C. The pediatrician (primary care provider notification process)
- D. The economic status of the children

Answer: A

Explanation:
Children are avulnerable populationrequiring additional protections.
* 45 CFR 46.408(a):Requires "adequate provisions for soliciting the assent of the children, when in the judgment of the IRB, the children are capable of providing assent."
* 45 CFR 46.402:Defines "assent" as a child's affirmative agreement to participate.
* IRBs must consider theage, maturity, and psychological stateof the children when determining assent capability.
Economic status (B) is irrelevant to assent. Physiological status (C) pertains to eligibility, not assent. Provider notification (D) may be local practice but not required by regulation.
Correct answer:A (Psychological status).
References:
45 CFR 46.402-408.

NEW QUESTION # 93
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