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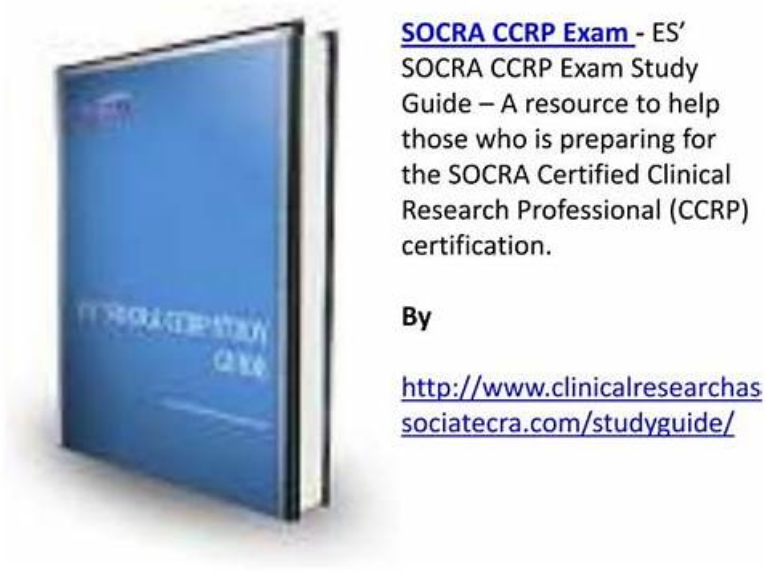

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SOCRA CCRP Exam Syllabus Topics:

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.

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q28-Q33):

NEW QUESTION # 28
According to the CFR, when children who are wards of the state are enrolled into a clinical trial, what is required?

- A. The IRB/IEC must include a member who advocates for the children
- B. Assenting children must self-represent
- C. Each child must have a patient advocate
- D. The investigator must represent the children

Answer: A

Explanation:
Children who are wards of the state receiveadditional protectionsin clinical research.
* 45 CFR 46.409(b):For research involving wards, "the IRB shall require appointment of an advocate for each child, in addition to any guardian or other advocate who would ordinarily be provided."
* The advocate must have background and experience to act in the child's best interest and cannot be associated with the research.
Thus, anIRB-appointed advocateis mandatory to ensure independent representation of the ward's rights.
References:45 CFR 46.409(b).

NEW QUESTION # 29
According to the CFR and the ICH GCP Guideline, which of the following must be submitted to the IRB after completion of the trial at the site?

- A. The monitoring close-out visit report
- B. The final subject enrollment log
- C. The final report
- D. The data safety monitoring summary

Answer: C

Explanation:
When a trial ends at a site, the investigator has an obligation to submit a final report to the IRB/IEC. This is outlined in both ICH and CFR:
ICH E6(R2) 4.13: "Upon completion of the trial, the investigator should provide the IRB/IEC with a summary of the trial's outcome."
21 CFR 312.66: Requires investigators to "report to the IRB all changes in the research activity and all unanticipated problems involving risk, and to provide reports at the end of the study." The final report provides closure and documentation that the study was conducted ethically and in compliance with regulatory standards. Other documents listed in the options (monitoring reports, DSMB summaries, subject logs) may be retained by the sponsor or site, but they are not mandated for IRB submission.
Thus, the correct answer is A (Final Report). This ensures the IRB/IEC has an accurate record of study completion, outcome, and compliance with ethical oversight.
References:
ICH E6(R2), §4.13 (Final reporting to IRB/IEC).
21 CFR 312.66 (IRB review and reporting).

NEW QUESTION # 30
Which of the following identifies content that should be included in a clinical research protocol?

- A. Criteria for the selection of an investigator
- B. A summary of findings of nonclinical studies that potentially have clinical significance

- C. Standard operating procedures for data collection
- D. IRB/IEC approval and meeting minutes

Answer: B

Explanation:
Theprotocolmust provide scientific rationale, including prior nonclinical findings that justify human research.
* ICH E6(R2) 6.2.2:"The protocol should include... a summary of findings from nonclinical studies that potentially have clinical significance and from clinical trials that are relevant to the trial." Other listed options belong elsewhere:
* IRB approvals (A) are separate administrative records.
* SOPs for data collection (B) are sponsor-level procedural documents.
* Investigator selection (C) is a sponsor's responsibility, not protocol content.
Thus, the correct answer isD (Summary of nonclinical findings with clinical relevance).
References:
ICH E6(R2), §6.2.2 (Protocol contents).

NEW QUESTION # 31
A pharmaceutical company is developing a biologic study. In accordance with ICH, which of the following items should be included in an investigator's brochure (IB)?

- A. Dispensing instructions
- B. Lab draw requirements
- C. Results of recent nude mouse study
- D. Schedule of events

Answer: C

Explanation:
TheInvestigator's Brochure (IB)compilesclinical and nonclinical dataon an investigational product relevant to human study.
* ICH E6(R2) 7.2.3:The IB should summarizenonclinical pharmacology, toxicology, pharmacokinetics, and efficacy data, including results of animal studies.
* ICH E6(R2) 7.2.4:It should also includeavailable clinical trial dataand safety experience.
The "results of recent nude mouse study" (B) are nonclinical data, which appropriately belong in the IB. Lab draw requirements (A), dispensing instructions (C), and schedules of events (D) are operational/procedural and are found in theprotocol, not the IB.
Thus, the correct answer isB (Results of recent nude mouse study).
References:
ICH E6(R2), §7.2.3-7.2.4 (Contents of Investigator's Brochure).

NEW QUESTION # 32
A Phase I study of a new blood pressure medication has been submitted for initial approval to an IRB/IEC. In accordance with the CFR, the IRB/IEC must consider which of the following criteria when determining whether to approve the study?

- A. The funding source for the trial
- B. The equitability of the selection of subjects
- C. The educational background of the study team
- D. The availability of the patient population

Answer: B

Explanation:
When reviewing protocols, IRBs/IECs are primarily responsible forsafeguarding human subjectsby evaluating risks, benefits, and fairness in subject selection.
* 21 CFR 56.111(a)(3):"In making its determination the IRB shall determine that... selection of subjects is equitable."
* 45 CFR 46.111(a)(3):Repeats this requirement, emphasizing fairness across gender, race, age, and socioeconomic status.
Other options:
* Patient population availability (A) is afeasibility issue, addressed by investigators and sponsors, not IRBs.
* Education of the study team (C) is confirmed by thesponsor and investigator, not IRB.
* Funding sources (D) may raise conflict of interest concerns, but they are not IRB approval criteria per federal regulations.
Thus, IRBs focus onjustice and fairness in subject selectionas part of the Belmont Report principles.

References:
21 CFR 56.111(a)(3).
Belmont Report (Justice principle).

NEW QUESTION # 33

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