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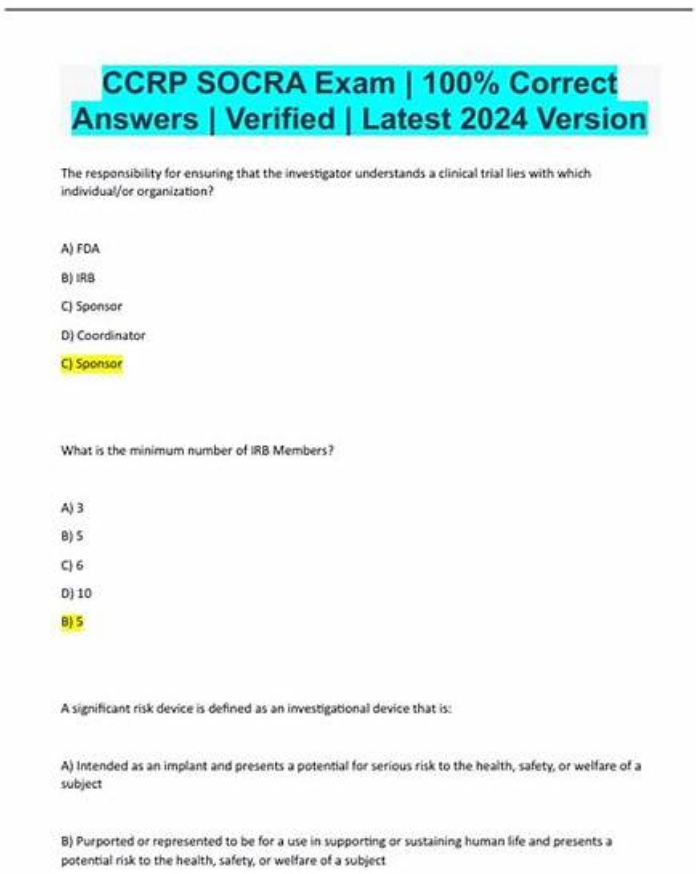

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The responsibility for ensuring that the investigator understands a clinical trial lies with which individual/or organization?

A) FDA
B) IRB
C) Sponsor
D) Coordinator
C) Sponsor

What is the minimum number of IRB Members?

A) 3
B) 5
C) 6
D) 10
B) 5

A significant risk device is defined as an investigational device that is:

A) Intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject

B) Purported or represented to be for a use in supporting or sustaining human life and presents a potential risk to the health, safety, or welfare of a subject

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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 (Q36-Q41):

NEW QUESTION # 36
The reviewing IRB/IEC determined that a minimal risk sponsor-investigator study is exempt from IRB/IEC review. How often, if ever, is the sponsor-investigator required to submit a continuing review to the IRB/IEC?

- A. Exactly one time, at study closure
- B. There is no such requirement
- C. Every year
- D. Every two years

Answer: B

Explanation:
Minimal risk studiesmay qualify for exemption or expedited review under45 CFR 46.101(b).
* 45 CFR 46.109(f):"Unless an IRB determines otherwise, continuing review of research is not required for research eligible for expedited review and determined to involve no more than minimal risk."
* ICH E6(R2) 3.1.4:Requires IRB review for clinical trials, but exemptions exist for minimal risk studies.
Therefore, once exempted, there isno requirement for continuing review, unless specifically required by the IRB. Submission at closure is optional depending on institutional policy but not a federal requirement.
Thus, the correct answer isD (No such requirement).
References:

45 CFR 46.109(f) (Exempt and expedited reviews).

NEW QUESTION # 37
In accordance with the CFR, the sponsor (who is not a sponsor-investigator) is responsible for which of the following?

- A. Overseeing the administration of the investigational drug to the subjects
- B. Ensuring that the FDA and all participating investigators are promptly informed of significant new adverse effects or risks with respect to the drug
- C. Maintaining case histories that record all observations and other data pertinent to the investigation
- D. Submitting progress reports to the reviewing IRB/IEC

Answer: B

Explanation:
Sponsors are responsible for distributing safety updates across all investigators and the FDA.
* 21 CFR 312.55(b):"The sponsor shall promptly notify all participating investigators, and the FDA, of new significant adverse effects or risks with respect to the drug." Other responsibilities fall elsewhere:
* Case histories (C) are maintained by investigators (21 CFR 312.62(b)).
* Progress reports to IRBs (D) are the investigator's duty (21 CFR 312.66).
* Administration of investigational drug (A) is managed by the investigator at site level.
Thus, the correct answer isB (Ensuring FDA and investigators are promptly informed).
References:
21 CFR 312.55(b) (Sponsor notification requirements).

NEW QUESTION # 38
During an internal compliance review, the site study team identified that a protocol-required blood sample collection was not obtained for a majority of the subjects enrolled. In accordance with the ICH GCP Guideline, the clinical investigator should:

- A. Suspend all trial-related activities until the events of the deviation have been mitigated
- B. Assign another investigator to perform sample collections until an internal investigation is completed
- C. Document and explain the deviation from the protocol
- D. Immediately report the observation to the regulatory authority

Answer: C

Explanation:
ICH directs investigators todocument and explainany deviation, with prompt reporting to IRB/IEC only when deviations are implemented to eliminate immediate hazards or as required. Exact extracts:
* ICH E6(R2) 4.5.3: "The investigator should document and explain any deviationfrom the approved protocol."
* ICH E6(R2) 3.3.7 & 4.5.2 (paraphrased): deviations to eliminate immediate hazards must be reported as soon as possible.Here, absent immediate hazard, the required action is documentation and explanation (B).
References:
ICH E6(R2) Good Clinical Practice, §4.5.3 (Compliance with protocol; deviations).
ICH E6(R2) §3.3.7; §4.5.2 (Reporting deviations implemented to eliminate immediate hazards).

NEW QUESTION # 39
Before approving a research protocol, an IRB/IEC must determine compliance with which of the following requirements?

- A. A plan for the publication of study results is in place
- B. The sponsor is qualified to provide oversight of the trial
- C. The investigator has adequate access to patients eligible for the trial
- D. The selection of subjects is equitable

Answer: D

Explanation:
IRB/IEC review focuses onethical protection of human subjects. Equitable subject selection is a cornerstone principle.
* 45 CFR 46.111(a)(3):"In order to approve research... the IRB shall determine that:Selection of subjects is equitable."

* ICH E6(R2) 3.1.2:"The IRB/IEC should safeguard the rights, safety, and well-being of all trial subjects... with particular attention to trials that may include vulnerable subjects." Publication plans (A) are not required by IRBs. Access to patients (C) and sponsor qualifications (D) are evaluated by sponsors, not IRBs. The IRB's role is ensuring fairness, minimizing coercion, and protecting vulnerable populations.
Thus, the correct answer isB (The selection of subjects is equitable).
References:
45 CFR 46.111(a)(3) (Equitable subject selection).
ICH E6(R2), §3.1.2 (IRB/IEC role).

NEW QUESTION # 40
Which of the following identifies content that should be included in a clinical research protocol?

- A. IRB/IEC approval and meeting minutes
- B. Criteria for the selection of an investigator
- C. A summary of findings of nonclinical studies that potentially have clinical significance
- D. Standard operating procedures for data collection

Answer: C

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 # 41
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