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SOCRA CCRP Exam Syllabus Topics:

Topic	Details
Topic 1	<ul style="list-style-type: none">• 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.

Topic 2	<ul style="list-style-type: none"> • 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.
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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q76-Q81):

NEW QUESTION # 76

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

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

Answer: B

Explanation:

Children who are wards of the state receive additional protections in 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, an IRB-appointed advocate is mandatory to ensure independent representation of the ward's rights.

References: 45 CFR 46.409(b).

NEW QUESTION # 77

In accordance with the Belmont Report, obtaining voluntary informed consent from subjects prior to enrolling them in a clinical trial is an example of which of the following ethical principles?

- A. Justice
- B. Do no harm
- C. Beneficence
- **D. Respect for persons**

Answer: D

Explanation:

The Belmont Report (1979) established three key ethical principles:

* **Respect for Persons:** Requires informed consent, recognition of autonomy, and protection of vulnerable individuals.

* **Beneficence:** Obligation to maximize benefits and minimize harm.

* **Justice:** Ensuring fairness in subject selection and distribution of research burdens/benefits.

Voluntary informed consent embodies Respect for Persons, as subjects are given adequate information and freedom of choice. "Do no harm" (A) is a Hippocratic principle but not Belmont terminology.

Thus, the correct answer is B (Respect for persons).

References:

The Belmont Report (1979), Part B: Basic Ethical Principles.

NEW QUESTION # 78

Protecting prisoners' rights to voluntarily participate in research is an example of which Belmont principle?

- A. Justice
- B. Beneficence
- C. Respect for Persons
- D. Dignity

Answer: C

Explanation:

* Belmont Report: "Respect for Persons" incorporates two ethical convictions: treating individuals as autonomous agents and protecting those with diminished autonomy (e.g., prisoners).

* Prisoners require special safeguards because of restricted liberty and potential coercion.

References: Belmont Report (1979).

NEW QUESTION # 79

A sponsor-investigator implemented a protocol deviation in a device trial to eliminate an immediate hazard. Before applying this change to all subjects, what must occur?

- A. Train sub-investigators
- B. Document change in study file
- C. Obtain IRB/IEC approval
- D. Inform all subjects

Answer: C

Explanation:

* 21 CFR 812.35(a)(2): Allows deviation without prior approval only to eliminate immediate hazards.

* Before applying broadly, IRB approval must be obtained.

References: 21 CFR 812.35(a)(2).

NEW QUESTION # 80

A sponsor is permitted to charge for an investigational drug but must provide what documentation?

- A. Orphan product evidence
- B. IRB attestation of institutional cost burden
- C. Evidence of potential clinical benefit and significant advantage
- D. CMS approval letter

Answer: C

Explanation:

* 21 CFR 312.8(b): Sponsors may charge for investigational drugs only if they demonstrate that the drug provides potential clinical benefit and a significant advantage over existing therapy.

* FDA must approve charging requests.

References: 21 CFR 312.8(b).

NEW QUESTION # 81

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