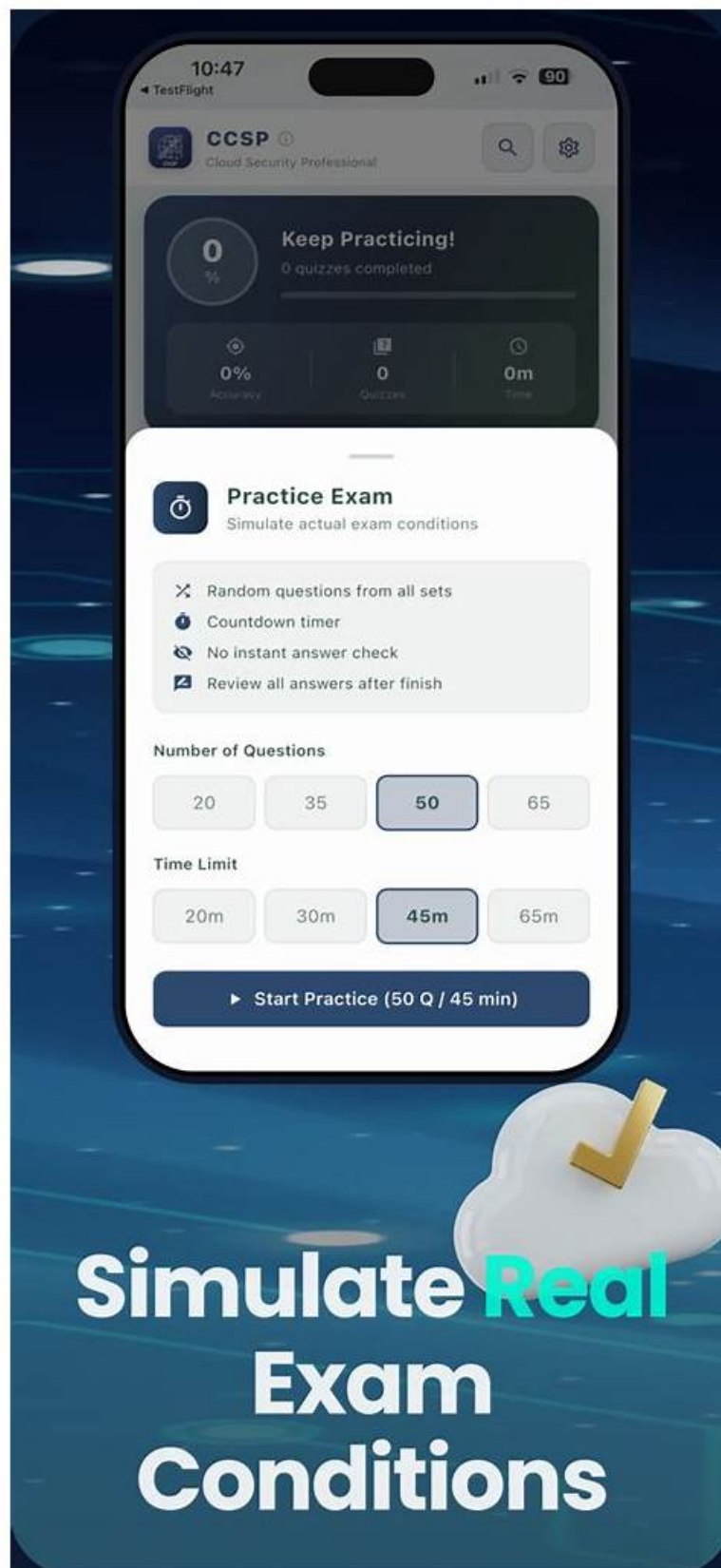


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SOCRA CCRP Exam Syllabus Topics:

Topic	Details
Topic 1	<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.
Topic 2	<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.

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q56-Q61):

NEW QUESTION # 56

Which of the following should a clinical investigator include in a submission to an IRB/IEC for a Phase IV drug study?

- A. The investigator's clinical trial agreement with the sponsor
- B. The drug development and marketing plan
- **C. The amount of payments and compensation to subjects**
- D. The itemized study budget

Answer: C

Explanation:

For IRB/IEC submissions, investigators must disclose subject-related information that may impact voluntariness or fairness of participation.

* 21 CFR 56.111(a)(3):The IRB must ensure that subject selection is equitable.
 * 21 CFR 50.25(a)(3):Requires disclosure of "any compensation and/or medical treatments available if injury occurs."
 * ICH E6(R2) 4.8.10(n):Informed consent should describe "any compensation and/or reimbursement to subjects."
 Thus,compensation amounts must be reviewed by IRB/IEC to ensure they are not coercive or excessive.
 Budgets (A), marketing plans (C), and contracts (D) are administrative and not part of IRB submission requirements.
 Correct answer:B (The amount of payments and compensation to subjects).
 References:
 21 CFR 50.25(a)(3).
 ICH E6(R2), §4.8.10(n).

NEW QUESTION # 57

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. Beneficence
- C. Respect for persons
- D. Do no harm

Answer: C

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 # 58

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

Answer: D

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 is A (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 # 59

A revised protocol added genomic testing to banked tissue samples. Before shipping samples, what must the site do?

- A. Notify enrolled subjects
- B. Execute material transfer agreement
- **C. Obtain IRB/IEC approval for revised protocol and ICF**
- D. Ship under dangerous goods requirements

Answer: C

Explanation:

* 21 CFR 56.109(a):IRB must review and approve any protocol amendments before implementation.

* ICH E6(R2) 4.5.2:Changes affecting subjects (e.g., genomic testing) require IRB/IEC approval and updated consent.

Thus, site must first obtain IRB approval for revised protocol and ICF.

References:21 CFR 56.109(a); ICH E6(R2) §4.5.2.

NEW QUESTION # 60

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

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

Answer: D

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 # 61

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