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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q48-Q53):

NEW QUESTION # 48

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

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

Answer: D

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 an FDA violation.

References: 21 CFR 812.7.

NEW QUESTION # 49

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

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

Answer: A

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 # 50

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

Answer: B

Explanation:

Children are a vulnerable population requiring 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 the age, maturity, and psychological state of 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 # 51

According to 21 CFR Part 11, each electronic signature must be unique and:

- **A. Cannot be reused or reassigned**
- B. Transferable to family
- C. Identical to handwritten signature
- D. Reassignable after validation

Answer: A

Explanation:

* 21 CFR 11.100(a): Requires that electronic signatures be "unique to one individual and shall not be reused or reassigned to anyone"

else."

* This ensures accountability and audit trail integrity.

References: 21 CFR 11.100(a).

NEW QUESTION # 52

For a Significant Risk device study, an investigator must report within 5 working days which event?

- A. Unanticipated adverse effect
- B. Completion of investigation
- C. **Emergency deviation**
- D. Withdrawal of FDA approval

Answer: C

Explanation:

* 21 CFR 812.150(a)(4): Any deviation from investigational plan made to protect the life or physical well-being of a subject in an emergency must be reported to the sponsor and IRB within 5 working days.

* Unanticipated adverse device effects have a 10-day reporting window.

References: 21 CFR 812.150(a)(4).

NEW QUESTION # 53

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