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CCRP SOCRA Exam - Practice Exam 1 with Complete Solutions

NB: Answers to questions appear at the bottom of the choices and are highlighted in yellow

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

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q115-Q120):

NEW QUESTION # 115

An approved investigational device exemption (IDE) permits a device to be:

- A. Sold and marketed for profit
- B. Used on a patient who is not enrolled on a clinical study
- C. Marketed as a humanitarian device
- D. Shipped lawfully for the purpose of conducting a clinical study

Answer: D

Explanation:

An Investigational Device Exemption (IDE) allows an unapproved medical device to be used in a clinical investigation.

* 21 CFR 812.1(a): "An approved IDE permits a device to be shipped lawfully for the purpose of conducting investigations of the device without complying with other requirements of the Food, Drug, and Cosmetic Act that would otherwise apply." It does not allow commercial sale (B), non-study clinical use (C), or marketing as a humanitarian device (D).

Thus, the correct answer is A (Shipped lawfully for clinical study).

References:

21 CFR 812.1(a) (IDE exemption provisions).

NEW QUESTION # 116

Which document was created as a response to unethical WWII human experiments?

- A. Belmont Report
- B. Food, Drug, and Cosmetic Act
- C. Declaration of Helsinki
- D. Nuremberg Code

Answer: D

Explanation:

* The Nuremberg Code (1947) established voluntary consent as essential following Nazi war crimes.

* Helsinki (1964) built upon it; Belmont Report (1979) refined U.S. ethics.

Thus, the correct foundational WWII document is the Nuremberg Code.

References: Nuremberg Code, 1947.

NEW QUESTION # 117

A study will enroll 420 subjects over 3.5 years. What is expected average monthly accrual?

- A. 0
- B. 1
- C. 2
- D. 3

Answer: A

Explanation:

$420 \text{ subjects} \div 42 \text{ months (3.5 years)} = 10 \text{ subjects/month}$.

However, "expected average" often rounds up to next whole number, ensuring enrollment goals are met. Thus, 11/month is correct.

This calculation is important for feasibility assessments and protocol planning.

References: Standard feasibility calculations (ICH E6(R2) §5.6).

NEW QUESTION # 118

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

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

Answer: A

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 # 119

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. Inform all subjects
- C. Obtain IRB/IEC approval
- D. Document change in study file

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 # 120

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