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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q60-Q65):

NEW QUESTION # 60

A subject enrolled in a drug clinical trial has withdrawn from the study. In accordance with ICH GCP, which of the following documents should be consulted to determine whether the participant should be replaced?

- A. The data safety monitoring plan

- B. The Investigator's Brochure
- C. The informed consent document
- **D. The protocol**

Answer: D

Explanation:

The protocol governs all trial conduct, including whether subjects should be replaced when they withdraw.

* ICH E6(R2) 6.0: The protocol must contain "detailed information on trial design, methodology, statistical considerations, and the organization of the trial."

* ICH E6(R2) 6.9.2: The section on "Subject withdrawal or discontinuation" specifies "whether and under what conditions subjects may be replaced." Other documents serve different functions: the DSM plan (A) manages safety oversight, the IB (C) summarizes product background, and the consent form (D) explains subject rights but does not guide study conduct. Only the protocol provides the operational answer regarding replacement.

Thus, the correct answer is B (The protocol).

References:

ICH E6(R2), §6.0 (Protocol content).

ICH E6(R2), §6.9.2 (Subject withdrawal/discontinuation).

NEW QUESTION # 61

A study coordinator is preparing an IRB submission for a Phase II oncology study. Which document must be included?

- **A. Recruitment materials**
- B. List of potential subjects
- C. Record storage plan
- D. Case report forms

Answer: A

Explanation:

* ICH E6(R2) 3.1.2 & FDA Recruitment Guidance (1998): Recruitment materials must be reviewed by IRB to ensure no coercion or misleading claims.

* CRFs and storage plans are sponsor/site tools, not IRB-reviewed documents.

References: ICH E6(R2) §3.1.2; FDA Recruitment Guidance, 1998.

NEW QUESTION # 62

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

- A. Marketed as a humanitarian device
- B. Used on a patient who is not enrolled on a clinical study
- C. Sold and marketed for profit
- **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 # 63

A pharmaceutical company is developing a biologic study. In accordance with ICH, which of the following items should be included in an investigator's brochure (IB)?

- A. Schedule of events
- B. Dispensing instructions
- C. Lab draw requirements
- **D. Results of recent nude mouse study**

Answer: D

Explanation:

The Investigator's Brochure (IB) compiles clinical and nonclinical data on an investigational product relevant to human study.

* ICH E6(R2) 7.2.3: The IB should summarize nonclinical pharmacology, toxicology, pharmacokinetics, and efficacy data, including results of animal studies.

* ICH E6(R2) 7.2.4: It should also include available clinical trial data and safety experience.

The "results of recent nude mouse study" (B) are nonclinical data, which appropriately belong in the IB. Lab draw requirements (A), dispensing instructions (C), and schedules of events (D) are operational/procedural and are found in the protocol, not the IB.

Thus, the correct answer is B (Results of recent nude mouse study).

References:

ICH E6(R2), §7.2.3-7.2.4 (Contents of Investigator's Brochure).

NEW QUESTION # 64

In an IND study, the specified dosage of an investigational product is 2 mg twice a day for 10 days. The product is available in 1 mg tablets. The subject was given 45 tablets and was instructed to take 2 mg of the product twice a day for 10 days. How many tablets should the subject have after the 10 days?

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

Answer: B

Explanation:

This question tests drug accountability and dosing calculation, which is central to ICH E6(R2) 4.6 (Investigational product management). Subjects must receive the correct supply and any discrepancy must be reconciled.

The prescribed regimen is 2 mg twice daily = 4 mg per day. With 1 mg tablets, this equals 4 tablets daily.

Over 10 days, the subject should consume 40 tablets ($4 \times 10 = 40$). Since 45 tablets were dispensed, the subject should have 5 tablets remaining after 10 days.

Accurate accountability ensures trial integrity and subject safety. Investigators are responsible for maintaining investigational product (IP) records, including dispensing, usage, and returns. According to ICH:

4.6.3: "The investigator/institution should maintain records of the product's delivery to the trial site, the inventory, the use by each subject, and the return to the sponsor or alternative disposition."

4.6.5: "The investigator should ensure that investigational products are used only in accordance with the approved protocol." Thus, the correct answer is C (5 tablets remain). This reflects proper dosing compliance and highlights the importance of meticulous IP tracking in clinical trials.

References:

ICH E6(R2), §4.6 (Investigational Product(s)).

NEW QUESTION # 65

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