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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q46-Q51):

NEW QUESTION # 46

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. Document change in study file
- B. Train sub-investigators
- 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 # 47

A research site was invited to participate in an investigational drug study. Which of the following parties is responsible for determining the risk-benefit ratio at the site?

- A. The clinical investigator
- B. The sponsor
- C. The IRB/IEC
- D. The site's legal counsel

Answer: C

Explanation:

The risk-benefit ratio is a core responsibility of the IRB/IEC.

* 21 CFR 56.111(a)(2): "Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result."

* ICH E6(R2) 3.1.2: IRB/IEC must safeguard rights, safety, and well-being of subjects, with special attention to risk-benefit evaluation.

Investigators (A) provide medical judgment but do not formally approve the risk-benefit balance. Sponsors (D) design studies but must submit to IRB for independent review. Legal counsel (C) is not part of the scientific/ethical evaluation.

Thus, IRB/IEC is directly responsible for approving the risk-benefit ratio.

References:

21 CFR 56.111(a)(2).

ICH E6(R2), §3.1.2.

NEW QUESTION # 48

A sponsor became aware of a new serious adverse event related to a drug. Who must be notified in addition to FDA?

- A. All IRBs/IECs of record
- B. All investigational pharmacists
- C. OHRP
- D. All participating investigators

Answer: D

Explanation:

* 21 CFR 312.32(c)(1)(ii): Sponsors must notify all participating investigators of any serious and unexpected suspected adverse reactions.

* Investigators then inform IRBs and subjects as appropriate.

References: 21 CFR 312.32(c)(1)(ii).

NEW QUESTION # 49

In accordance with the ICH GCP Guideline, which of the following can an Independent Data Monitoring Committee provide?

- A. Suggestions for a new trial design
- B. The selection of qualified investigators
- C. Recommendations to stop a trial
- D. An initial review and approval of a trial

Answer: C

Explanation:

An Independent Data Monitoring Committee (IDMC or DSMB) is a group of independent experts established to review accumulating safety and efficacy data during a trial. Their main role is to ensure subject protection and trial integrity.

* ICH E6(R2) 5.5.1: "The sponsor may consider establishing an independent data-monitoring committee (IDMC) to assess the progress of a clinical trial, including the safety data and the critical efficacy endpoints, and to recommend to the sponsor whether to continue, modify, or stop a trial." Thus, DSMBs/IDMCs do not perform trial approvals (A), do not design trials (C), and do not select investigators (D). Their authority is strictly advisory, providing recommendations to sponsors about safety and whether continuation of the study is ethically justified. The sponsor makes the final decision, but DSMB recommendations are highly influential.

Therefore, the correct answer is B (Recommendations to stop a trial).

References:

ICH E6(R2), §5.5.1 (Independent Data Monitoring Committees).

NEW QUESTION # 50

Which case history documents must be at both sponsor and site?

- A. Medical records
- B. Study visit notes
- C. Signed informed consent forms
- D. Case report forms (CRFs)

Answer: D

Explanation:

* ICH E6(R2) 1.11: CRFs are documents used to record protocol-required data reported to sponsor.

* Sites keep originals; sponsor retains copies. Consent forms and medical records stay at site only.

References: ICH E6(R2), §1.11.

NEW QUESTION # 51

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