SOCRA

CCRP

Certified Clinical Research Professional (CCRP)

Latest Version: 6.0

Question: 1

Which of the following is an example of an additional protection required when conducting research on children?

A. There must be an impartial advocate present during the consent process
B. The investigator must obtain age-appropriate assent as determined by the IRB/IEC
C. Parents must be present during all procedures
D. The study must be approved by a central pediatric IRB

Answer: B

Explanation:
Children are a vulnerable population. U.S. regulations require IRB/IEC judgment about when and how assent is obtained, in addition to parental permission. Exact extracts:
45 CFR 46.408(a): "The IRB shall determine … whether and to what extent children are capable of providing assent."
ICH E6(R2) 4.8.12: "Where a subject is unable to give consent personally, assent should be obtained when appropriate, in accordance with applicable regulatory requirement(s)."
Thus, the additional protection is IRB-determined, age-appropriate assent (B). Options A, C, and D are not universal requirements for all pediatric research.
Reference:
ICH E6(R2) Good Clinical Practice, §4.8.12 (Informed consent/assent).
45 CFR 46 Subpart D—Additional Protections for Children, §46.408(a).
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Question: 2

A subject currently on a clinical trial was hospitalized for 2 days due to a SAE. The subject reported the hospitalization to the investigator at the next study visit. According to the ICH GCP Guideline, when should the investigator report the SAE to the sponsor?

A. Immediately
B. Within 7 working days
C. Within 10 working days
D. Within 15 working days

Answer: A

Explanation:

ICH requires immediate reporting of all SAEs to the sponsor (except those protocol-identified as not requiring immediate reporting). Exact extract:
ICH E6(R2) 4.11.1: “The investigator should report all serious adverse events immediately to the sponsor except for those SAEs that the protocol… identifies as not needing immediate reporting.”
Therefore, “Immediately” (A) is correct. The other timeframes are not aligned with ICH GCP for initial SAE notification from investigator to sponsor.
Reference:
ICH E6(R2) Good Clinical Practice, §4.11.1 (Safety reporting by investigators).
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Question: 3

In accordance with the ICH GCP Guideline, when a sponsor transfers trial-related duties and functions to a contract research organization (CRO), who is ultimately responsible for the quality and integrity of the trial data?

A. The investigator
B. The IRB/IEC
C. The CRO
D. The sponsor

Answer: D

Explanation:
Outsourcing does not shift ultimate responsibility away from the sponsor. Exact extract:
ICH E6(R2) 5.2.1: “A sponsor may transfer any or all of the sponsor’s trial-related duties… to a CRO, but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor.”
Hence, D is correct.
Reference:
ICH E6(R2) Good Clinical Practice, §5.2.1 (Sponsor/CRO).
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Question: 4

During an internal compliance review, the site study team identified that a protocol-required blood sample collection was not obtained for a majority of the subjects enrolled. In accordance with the ICH GCP Guideline, the clinical investigator should:

A. Suspend all trial-related activities until the events of the deviation have been mitigated
B. Document and explain the deviation from the protocol
C. Assign another investigator to perform sample collections until an internal investigation is completed
D. Immediately report the observation to the regulatory authority

Answer: B

Explanation:
ICH directs investigators to document and explain any deviation, with prompt reporting to IRB/IEC only when deviations are implemented to eliminate immediate hazards or as required. Exact extracts:
ICH E6(R2) 4.5.3: “The investigator should document and explain any deviation from the approved protocol.”
ICH E6(R2) 3.3.7 & 4.5.2 (paraphrased): deviations to eliminate immediate hazards must be reported as soon as possible.
Here, absent immediate hazard, the required action is documentation and explanation (B).
Reference:
ICH E6(R2) Good Clinical Practice, §4.5.3 (Compliance with protocol; deviations).
ICH E6(R2) §3.3.7; §4.5.2 (Reporting deviations implemented to eliminate immediate hazards).
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Question: 5

A coordinator for an ongoing industry-sponsored, multi-site Phase II clinical trial is taking an unexpected, long-term medical absence. The trial site retains coordinator services from an external source to support clinical trial activities. According to the ICH GCP Guideline, which of the following is responsible for implementing procedures to ensure the integrity of the clinical trial-related duties?

A. The sponsor
B. The investigator/institution
C. The IRB/IEC
D. The external source

Answer: B

Explanation:
The investigator/institution bears responsibility for site conduct, oversight of delegated tasks, and ensuring qualified, trained staff—regardless of employment source. Exact extracts:
ICH E6(R2) 4.1.1: “The investigator should be qualified… and have adequate resources to properly conduct the trial.”
ICH E6(R2) 4.1.5: “The investigator should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial-related duties and functions.”
ICH E6(R2) 4.2.5: “The investigator may delegate… but retains responsibility for the conduct of the trial at the site.”
Therefore, the investigator/institution (B) must implement procedures and oversight to maintain integrity of trial duties.
Reference:
ICH E6(R2) Good Clinical Practice, §4.1.1; §4.1.5; §4.2.5 (Investigator responsibilities; delegation and oversight).
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