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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 (Q14-Q19):

### NEW QUESTION # 14

In accordance with the ICH GCP Guideline, at what intervals should the on-site study monitoring be performed?

- A. At least weekly
- B. Once a year until study close-out
- C. In a timely manner before, during, and after the study
- D. Every 4-6 weeks until study close-out

**Answer: C**

Explanation:

Monitoring ensures trial integrity and subject safety.

\* ICH E6(R2) 5.18.3: "The sponsor should ensure that the trials are adequately monitored. The determination of the extent and nature of monitoring should be based on considerations such as the objective, purpose, design, complexity, blinding, size, and endpoints of the trial."

\* Monitoring must occur before (initiation visit), during (periodic), and after (closeout).

It is not limited to fixed weekly or monthly intervals (A, B) and not as infrequent as yearly (D). Instead, it is risk-adapted and flexible, but must cover all phases of the study.

Correct answer: C (Timely manner before, during, and after).

References:

ICH E6(R2), §5.18.3.

### NEW QUESTION # 15

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

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

**Answer: C**

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.

References:

ICH E6(R2) Good Clinical Practice, §4.8.12 (Informed consent/assent).

45 CFR 46 Subpart D-Additional Protections for Children, §46.408(a).=====

### NEW QUESTION # 16

In accordance with ICH, which of the following is an acceptable protocol review frequency for an IRB?

- A. 6 months

- B. 12 months
- C. 24 months
- D. 36 months

**Answer: B**

Explanation:

IRBs must review protocols at least annually to ensure ongoing subject protection.

\* 21 CFR 56.109(f): "An IRB shall conduct continuing review of research at intervals appropriate to the degree of risk, but not less than once per year."

\* ICH E6(R2) 3.1.4: "The IRB/IEC should conduct continuing review of each ongoing trial at intervals appropriate to the degree of risk, but at least once per year." This establishes 12 months as the minimum required interval. More frequent reviews (e.g., 6 months) may occur for higher-risk studies, but longer intervals (24-36 months) are not permitted.

Correct answer: B (12 months).

References:

21 CFR 56.109(f).

ICH E6(R2), §3.1.4.

#### NEW QUESTION # 17

A clinical investigator terminated a Phase IV drug study. In accordance with the ICH GCP Guidelines, which of the following documents should the clinical investigator maintain?

- A. The audit certificate
- B. The completed subject identification code list
- C. The master randomization list
- D. The final trial closeout monitoring report

**Answer: B**

Explanation:

Upon study closure, investigators must maintain documentation that allows subject data to be linked back if necessary. The Subject Identification Code List is a key essential document for ensuring traceability while maintaining confidentiality.

\* ICH E6(R2) 8.3.21: "Subject Identification Code List - A list of all subjects randomized to trial numbers, allowing investigator to identify each subject in case follow-up is required. This list should be kept in a confidential manner and retained for the maximum retention period."

\* ICH E6(R2) 8.4: Essential documents for investigators include items needed for subject identification, protocol compliance, and trial closure.

Other listed documents (randomization list, monitoring report, audit certificate) are maintained by the sponsor, not the investigator.

The subject code list ensures that in the event of a safety issue, regulatory authority queries, or subject withdrawal, the investigator can trace back records.

Thus, the correct answer is B (Completed Subject Identification Code List).

References:

ICH E6(R2), §8.3.21 (Essential documents: Subject identification code list).

ICH E6(R2), §8.4 (Essential documents for trial closure).

#### NEW QUESTION # 18

Which of the following would be considered an addendum to an investigator's brochure for an unapproved Investigational Product?

- A. Revisions to the risk section of the informed consent form
- B. A site-specific SAE report
- C. Product monograph updates
- D. A Suspected Unexpected Serious Adverse Reaction (SUSAR) report

**Answer: D**

Explanation:

The IB must be updated as new significant safety information emerges.

\* ICH E6(R2) 7.3: "The sponsor should revise the IB as soon as new, significant information becomes available."

\* ICH E2A: Requires sponsors to report Suspected Unexpected Serious Adverse Reactions (SUSARs) in expedited reports and

include them in IB updates or addenda.

A SUSAR report (B) represents new, unexpected, and serious safety information not previously documented, and therefore warrants inclusion as an IB addendum until the IB is formally updated.

Revised consent forms (A) are submitted to IRBs, not IBs. Site-specific SAE reports (C) remain at site /sponsor level, not in the IB. Product monograph updates (D) apply to approved products, not investigational ones.

Thus, the correct answer is B (SUSAR report).

References:

ICH E6(R2), §7.3 (Updating the Investigator's Brochure).

ICH E2A (Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

## NEW QUESTION # 19

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Scott Kelby talks about Camera Raw's adjustment tools, including adjusting CCRP individual areas of your photo, retouching portraits, using the graduated filter and special effects, and Photoshop killer tips.

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