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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 CCRP Exam Syllabus Topics:

Topic	Details

Topic 1	<ul style="list-style-type: none"> • Research Study Start-Up: This section of the exam measures the skills of Clinical Research Coordinators and covers the initial planning and setup of a clinical trial. It involves coordinating the development of the study protocol, ensuring it considers ethical guidelines and regulatory pathways like IND or IDE. It also includes creating essential study documents like informed consent forms and case report forms. The domain covers obtaining necessary approvals from stakeholders like the IRB and sponsor, selecting study sites, training staff, and ensuring the study's compliance with various laws. Additionally, it involves obtaining the research product and preparing all necessary tools and documentation for the study's commencement. • Research Study Implementation: This section of the exam measures the skills of Clinical Research Associates and covers the active management and execution of the clinical trial. It focuses on following the study protocol and standard operating procedures, managing the investigational product, and ensuring ongoing regulatory compliance. The domain includes identifying, documenting, and reporting any study anomalies such as adverse events or protocol deviations. It also involves managing subject recruitment, consent, and retention, as well as maintaining all study records and essential documents. Furthermore, it covers communicating with all study stakeholders and participating in study audits to ensure quality and adherence to regulations.
Topic 2	<ul style="list-style-type: none"> • Research Study Closure: This section of the exam measures the skills of Clinical Research Coordinators and covers the activities required to properly conclude a clinical trial. It involves participating in the study closeout visit to verify documentation and account for the investigational product. The domain also includes developing and submitting final closure reports to the IRB, study sponsor, regulatory authorities, and clinicaltrials.gov. Finally, it covers the procedures for archiving study records.

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q127-Q132):

NEW QUESTION # 127

Sponsor must maintain drug disposition records for how long after marketing approval?

- A. 3 years
- B. 1 year
- C. 2 years
- D. 5 years

Answer: C

Explanation:

* 21 CFR 312.57(c): "Sponsors shall retain records for 2 years after a marketing application is approved or if not approved, 2 years after shipment and delivery of investigational drug for investigation." References: 21 CFR 312.57(c).

NEW QUESTION # 128

Before approving a research protocol, an IRB/IEC must determine compliance with which of the following requirements?

- A. A plan for the publication of study results is in place
- B. The sponsor is qualified to provide oversight of the trial
- C. The investigator has adequate access to patients eligible for the trial

- **D. The selection of subjects is equitable**

Answer: D

Explanation:

IRB/IEC review focuses on ethical protection of human subjects. Equitable subject selection is a cornerstone principle.

* 45 CFR 46.111(a)(3): "In order to approve research... the IRB shall determine that: Selection of subjects is equitable."

* ICH E6(R2) 3.1.2: "The IRB/IEC should safeguard the rights, safety, and well-being of all trial subjects... with particular attention to trials that may include vulnerable subjects." Publication plans (A) are not required by IRBs. Access to patients (C) and sponsor qualifications (D) are evaluated by sponsors, not IRBs. The IRB's role is ensuring fairness, minimizing coercion, and protecting vulnerable populations.

Thus, the correct answer is B (The selection of subjects is equitable).

References:

45 CFR 46.111(a)(3) (Equitable subject selection).

ICH E6(R2), §3.1.2 (IRB/IEC role).

NEW QUESTION # 129

Which of the following adverse events occurring during a study of an investigational new drug would require the sponsor to notify the FDA as soon as possible but in no case later than seven calendar days after the initial receipt of the information?

- A. Aplastic anemia requiring hospitalization, mentioned in the investigator's brochure
- B. Death due to disease progression, mentioned in the investigator's brochure
- C. An infection not related to the investigational drug requiring hospitalization for antibiotic therapy
- **D. Death as a result of arrhythmias (irregular heart rhythm), not mentioned in the investigator's brochure and thought to be related to the use of the drug**

Answer: D

Explanation:

Sponsors must report serious, unexpected, and suspected adverse reactions (SUSARs) to the FDA.

* 21 CFR 312.32(c)(2): "Any adverse experience associated with the use of the drug that is both serious and unexpected shall be reported... as soon as possible but no later than 7 calendar days after the sponsor's initial receipt of the information, if it is fatal or life-threatening."

* ICH E2A 4.2: Requires expedited reporting of life-threatening or fatal SUSARs within 7 days.

Among the options, only (C) - death from arrhythmias not previously identified in the Investigator's Brochure and suspected to be drug-related - meets the definition of a SUSAR requiring 7-day expedited reporting. Events already listed in the IB (A, D) or unrelated to the drug (B) do not trigger expedited reporting.

Thus, the correct answer is C.

References:

21 CFR 312.32(c)(2) (Expedited safety reporting).

ICH E2A, §4.2 (Expedited reporting of fatal/life-threatening adverse events).

NEW QUESTION # 130

According to ICH GCP, sponsor-specific essential documents must be retained until:

- A. 5 years after last approval
- **B. 2 years after last approval and no pending applications**
- C. 3 years after last approval
- D. 25 years after last approval

Answer: B

Explanation:

* ICH E6(R2) 5.5.12 & 8.1: Essential documents must be retained 2 years after the last approval of a marketing application in an ICH region and until no applications are pending, or 2 years after discontinuation of development.

This ensures availability for inspection.

References: ICH E6(R2) §§5.5.12, 8.1.

NEW QUESTION # 131

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

Answer: C

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.

References:

ICH E6(R2) Good Clinical Practice, §4.1.1; §4.1.5; §4.2.5 (Investigator responsibilities; delegation and oversight).=====

NEW QUESTION # 132

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