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SOCRA CCRP Sample Questions with verified Answers.

Contract Research Organization ✓ A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions.

When a short form is used for informed consent the witness must sign the short form or the summary? ✓ False-they must sign both

What is FDA form 3454 ✓ Certification Financial Interests and Arrangements of Clinical Investigators

What are the three main basic ethical principles of the Belmont Report?
✓ Respect for persons.
Beneficence.
Justice.

Phase III ✓ Study Participants: 300 to 3,000 volunteers who have the disease or condition

Length of Study: 1 to 4 years

Purpose: Efficacy and monitoring of adverse reactions

Phase I ✓ 20 to 100 healthy volunteers or people with the disease/condition.

Length of Study: Several months

Purpose: Safety and dosage

Phase II ✓ Study Participants: Up to several hundred people with the disease/condition.

Length of Study: Several months to 2 years

Purpose: Efficacy and side effects

The main concept of 21 CFR 50 is ✓ protection of human subjects

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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.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q92-Q97):

NEW QUESTION # 92

A sponsor's monitor is conducting a site selection visit for an interventional drug trial. In accordance with ICH GCP, which pharmacy drug storage facility information should be collected in order to determine whether the site could be selected for the trial?

- A. Available storage square footage
- B. Storage facility temperature range**
- C. Storage cost
- D. Number of staff members

Answer: B

Explanation:

Drug storage conditions are essential to maintaining investigational product (IP) integrity. According to ICH:

* ICH E6(R2) 5.13.3:"The sponsor should ensure that investigational products are stored... under appropriate conditions as specified by the sponsor and in accordance with applicable regulatory requirement(s)."

* ICH E6(R2) 4.6.4:"The investigator/institution should store the investigational product(s) as specified by the sponsor (and in accordance with applicable regulatory requirement(s)), and ensure that product (s) are used only in accordance with the approved protocol." During site qualification/selection, the monitor evaluates storage conditions - particularly temperature ranges- to ensure the site can meet the stability requirements for the IP. Factors like staff numbers, space, and cost are operational considerations but not regulatory determinants of site qualification.

Thus, the correct answer is C (Storage facility temperature range). This ensures compliance with sponsor specifications, product stability, and ultimately subject safety.

References:

ICH E6(R2), §5.13.3 (Product storage requirements).

ICH E6(R2), §4.6.4 (Investigator product storage responsibilities).

NEW QUESTION # 93

A study team is preparing to initiate a Phase II trial for a novel colon cancer therapy. By signing the Form FDA 1572, the investigator is certifying that the investigator has:

- A. Read and understood the investigator's brochure
- B. Completed other relevant research projects
- C. Obtained malpractice insurance
- D. Confirmed that the site's SOPs are in place

Answer: A

Explanation:

Form FDA 1572 is the "Statement of Investigator" for IND studies.

* 21 CFR 312.53(c)(1)(vi)(b):Requires investigators to "read and understand the Investigator's Brochure."

* By signing, the investigator also agrees to comply with regulations, maintain records, and supervise study conduct. Other options (B-D) are not part of 1572 requirements.

Correct answer:A.

References:

21 CFR 312.53(c)(1)(vi)(b).

NEW QUESTION # 94

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. An initial review and approval of a trial
- C. The selection of qualified investigators
- D. Recommendations to stop a trial

Answer: D

Explanation:

AnIndependent 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 anindependent 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/IDMCsdo not perform trial approvals (A),do not design trials (C), anddo 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 isB (Recommendations to stop a trial).

References:

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

NEW QUESTION # 95

Which of the following is considered a source document?

- A. Standard operating procedures (SOPs)
- B. The protocol
- C. The subject instruction sheet
- D. Pharmacy dispensing records

Answer: D

Explanation:

Source documentsare the original records where trial data are first recorded, from which Case Report Form (CRF) entries are verified.

* ICH E6(R2) 1.52:Defines source documents as "original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, pharmacy dispensing records, recorded data from automated instruments, etc.)."

* ICH E6(R2) 8.3.13:Requires maintenance of "source documents" to verify data integrity and allow monitoring/audits.

Pharmacy dispensing records (D) fit this definition, as they show initial data on investigational product dispensing and accountability. In contrast, subject instruction sheets (A) are communication tools, SOPs (B) are procedural guides, and the protocol (C) is a governing document, none of which qualify as original data records.

Therefore, the correct answer is D (Pharmacy dispensing records).

References:

ICH E6(R2), §1.52 (Definition of source documents).

ICH E6(R2), §8.3.13 (Source documents in essential documentation).

NEW QUESTION # 96

According to ICH GCP, who besides the sponsor should approve the financial aspects of a clinical trial?

- A. Investigator/institution
- B. Regulatory authority
- C. DSMB
- D. OHRP

Answer: A

Explanation:

* ICH E6(R2) 5.6.1: "The sponsor should ensure agreement from the investigator/institution on the financial aspects of the trial." This ensures transparency in compensation, reimbursement, and budget.

References: ICH E6(R2) §5.6.1.

NEW QUESTION # 97

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