

CCRP Test Sample Questions & CCRP Vce Pdf Training & CCRP Valid Test Simulator

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 Certified Clinical Research Professional (CCRP) Sample Questions (Q126-Q131):

NEW QUESTION # 126

In accordance with the ICH GCP Guideline and the CFR, who is directly responsible for ensuring that an IRB /IEC will conduct the initial and continuing review of a study?

- A. The study coordinator
- B. The monitor
- **C. The investigator**
- D. The sponsor

Answer: C

Explanation:

The investigator is directly responsible for ensuring that the IRB/IEC reviews and approves the research both initially and on a continuing basis. This responsibility is not delegable to the sponsor or study staff.

* ICH E6(R2) 4.4.1: "Before initiating a trial, the investigator/institution should have written and dated approval/favorable opinion from the IRB/IEC for the trial protocol, written informed consent form, consent form updates, and any other written information to be provided to subjects."

* 21 CFR 312.66: "An investigator shall assure that an IRB that complies with the requirements... will be responsible for the initial and continuing review and approval of the proposed clinical study." This means that while the sponsor submits documents to the FDA and oversees general compliance, the investigator has the obligation to obtain and maintain IRB approval at their site. The monitor or study coordinator may assist in documentation, but legal responsibility rests with the investigator.

Thus, the correct answer is C (The investigator).

References:

ICH E6(R2), §4.4.1 (Investigator responsibility before initiation).

21 CFR 312.66 (IRB responsibility in clinical investigations).

NEW QUESTION # 127

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

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

Answer: A

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 # 128

Which countries have officially adopted ICH-GCP E6(R2) as a standard, in addition to U.S., EU, Japan, Canada, and Australia?

- A. China
- **B. India**
- C. Switzerland
- D. Brazil

Answer: B

Explanation:

India has aligned national regulations with ICH-GCP.

* DCGI/ICMR Guidelines (India): Explicitly adopt ICH E6(R2) as part of its Good Clinical Practice standards. China and Brazil are harmonizing, but full official adoption is noted in India.

References: Indian GCP Guidelines (2017 revision).

NEW QUESTION # 129

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

- A. The selection of qualified investigators
- B. Suggestions for a new trial design
- **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 # 130

The sponsor withdrew an IND due to safety. Who must be notified promptly, in addition to FDA?

- A. Site coordinator
- **B. Reviewing IRBs/IECs**
- C. OHRP
- D. Investigational pharmacies

Answer: B

Explanation:

* 21 CFR 312.56(d): If an IND is withdrawn for safety, the sponsor must notify FDA and all participating investigators, who in turn notify IRBs.

* Ensures subjects are protected and sites stop enrollment.

References: 21 CFR 312.56(d).

NEW QUESTION # 131

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