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# **SOCRA CCRP Exam Syllabus Topics:**

Topic	Details
Topic 1	• 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	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 (Q106-Q111):**

# **NEW QUESTION # 106**

An investigator's responsibilities for conducting clinical trials include:

- A. Observing preclinical drug effects
- B. Administering or overseeing investigational drug administration
- C. Maintaining IRB meeting minutes
- D. Maintaining financial documentation for study staff

# Answer: B

#### Explanation:

- \* ICH E6(R2) 4.6.1:The investigator is responsible for investigational product accountability at the site.
- \* 21 CFR 312.61:Investigators must administer the investigational drug only to subjects under their supervision.

The IRB maintains meeting minutes (A), preclinical studies are sponsor tasks (B), and financial interest documentation (C) is covered under sponsor reporting. Thus,D is correct.

References:ICH E6(R2) §4.6.1; 21 CFR 312.61.

# **NEW QUESTION # 107**

According to the ICH GCP Guidelines, what is the purpose of source documents?

- A. To provide a record of subjects' investigational medical treatment
- B. To validate reports submitted to the IRB/IEC
- C. To establish diverse subject enrollment
- D. To validate insurance reimbursement

#### Answer: A

# Explanation:

\* ICH E6(R2) 1.52: Source documents are "original documents, data, and records... necessary for the reconstruction and evaluation

of the trial."

\* Their main role is to document treatment and verify CRFs.

References:ICH E6(R2), §1.52.

# **NEW QUESTION # 108**

An investigator received an updated informed consent form (ICF) from the sponsor for a study closed to enrollment. Subjects are only in long-term follow-up. The change related to frequent radiation imaging at screening, with no change to drug safety profile. Who must the investigator notify first?

- A. Participants in long-term follow-up
- B. No notification is required
- C. Sub-investigators
- D. The IRB/IEC

#### Answer: D

#### Explanation:

- \* 21 CFR 56.109(a):IRBs must review all changes to informed consent before implementation.
- \* ICH E6(R2) 4.8.2:If new information could affect willingness to continue, consent forms must be revised and approved by the IRB.

Even though screening is closed, the IRB/IEC must review the updated form before any subject re-consenting. References:21 CFR 56.109(a); ICH E6(R2) §4.8.2.

# **NEW QUESTION # 109**

Why would a Phase IV study be conducted?

- A. Different marketing strategy
- B. Different schedule of administration
- C. Different dosage
- D. Different off-label population

#### Answer: D

### Explanation:

Phase IV studies (post-marketing) examine real-world safety and effectiveness.

- \* ICH E8(R1):Describes Phase IV as "studies performed after drug approval to delineate additional information including the drug's risks, benefits, and optimal use."
- \* They often test drugs innew or broader populations beyond original approval.

While dosing and schedules are Phase I-III, Phase IV focuses onnew patient populations or long-term outcomes. References:ICH E8(R1).

# **NEW QUESTION #110**

In accordance with the Belmont Report, obtaining voluntary informed consent from subjects prior to enrolling them in a clinical trial is an example of which of the following ethical principles?

- A. Respect for persons
- B. Justice
- C. Do no harm
- D. Beneficence

#### Answer: A

## Explanation:

TheBelmont Report (1979)establishedthree key ethical principles:

- \* Respect for Persons:Requires informed consent, recognition of autonomy, and protection of vulnerable individuals.
- \* Beneficence: Obligation to maximize benefits and minimize harm.
- \* Justice:Ensuring fairness in subject selection and distribution of research burdens/benefits.

Voluntary informed consent embodiesRespect for Persons, as subjects are given adequate information and freedom of choice. "Do

no harm' (A) is a Hippocratic principle but not Belmont terminology. Thus, the correct answer isB (Respect for persons). References:

The Belmont Report (1979), Part B: Basic Ethical Principles.

# **NEW QUESTION # 111**

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