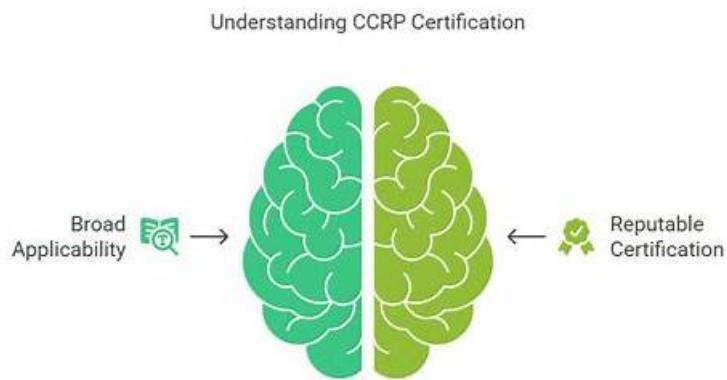


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## SOCRA CCRP Exam Syllabus Topics:

Topic	Details

Topic 1	<ul style="list-style-type: none"> <li>• 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.</li> </ul>
Topic 2	<ul style="list-style-type: none"> <li>• 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.</li> </ul>

## SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q122-Q127):

### NEW QUESTION # 122

In accordance with the CFR, a sponsor must submit a protocol amendment to the FDA for which of the following?

- A. The addition of a new test that is intended to improve monitoring the subject for an adverse effect
- B. A significant change in an investigator's financial interest in the investigational product
- C. The addition of a sub-investigator with the scientific training and expertise to conduct the investigation
- D. A change in the manufacturing site for the investigational product

### Answer: D

Explanation:

The U.S. Code of Federal Regulations (CFR) specifies when sponsors must notify FDA of changes to investigational drug studies under 21 CFR 312.30. A protocol amendment is required if there is:

A change to the protocol (e.g., objectives, design, subject population, dosing, or procedures).

The addition of a new investigator.

A change in the chemistry, manufacturing, or controls (CMC) that could significantly affect product quality or safety.

Among the listed options, a change in the manufacturing site (D) directly falls under significant manufacturing changes, requiring FDA submission. Changes in investigator financial interests (B) are covered under 21 CFR 54 and reported separately, not as protocol amendments. Addition of a sub-investigator (C) does not require a formal amendment, only site-level documentation and delegation log update. Addition of a monitoring test (A) may affect the protocol, but not necessarily mandate an amendment unless it changes objectives or subject safety endpoints.

Therefore, the correct answer is D. This ensures FDA oversight of product safety, efficacy, and compliance with CMC standards before investigational use.

References:

21 CFR 312.30 (Protocol amendments).

21 CFR 312.23(a)(7) (Chemistry, manufacturing, and controls information).

### NEW QUESTION # 123

A clinical investigator wants to publish a subject's unique results. The consent form did not mention publication. What is required?

- A. Consent from subject
- B. IRB chair approval

- C. Approval from monitor
- D. Nothing further

**Answer: A**

Explanation:

- \* ICH E6(R2) 4.8.10(n): Consent must include explanation about confidentiality and possible publication.
- \* If not included, specific subject consent must be obtained before publishing identifiable results.

Thus, subject's explicit permission is required.

References: ICH E6(R2) §4.8.10(n).

#### **NEW QUESTION # 124**

When can an IRB/IEC review a study using expedited review?

- A. For protocol changes involving more than minimal risk
- B. For initial review of a study using specimens with identifiers
- C. For initial review of Phase III IND protocol
- D. For minor changes to previously approved protocol

**Answer: D**

Explanation:

- \* 21 CFR 56.110(b): IRBs may use expedited review for minor changes in previously approved research.
- \* Expedited review cannot be used for initial reviews of high-risk protocols or major modifications.

Correct answer is D.

References: 21 CFR 56.110(b).

#### **NEW QUESTION # 125**

Which document was created as a response to unethical WWII human experiments?

- A. Declaration of Helsinki
- B. Belmont Report
- C. Nuremberg Code
- D. Food, Drug, and Cosmetic Act

**Answer: C**

Explanation:

- \* The Nuremberg Code (1947) established voluntary consent as essential following Nazi war crimes.

\* Helsinki (1964) built upon it; Belmont Report (1979) refined U.S. ethics.

Thus, the correct foundational WWII document is the Nuremberg Code.

References: Nuremberg Code, 1947.

#### **NEW QUESTION # 126**

Which of the following is considered a source document?

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

**Answer: C**

Explanation:

Source documents are 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 # 127

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It is universally accepted that the competition in the labor market has become more and more competitive in the past years. In order to gain some competitive advantages, a growing number of people have tried their best to pass the CCRP exam. Because a lot of people hope to get the certification by the related exam, now many leaders of companies prefer to the candidates who have the CCRP certification. In their opinions, the certification is a best reflection of the candidates' work ability, so more and more leaders of companies start to pay more attention to the CCRP certification of these candidates. If you also want to come out ahead, it is necessary for you to prepare for the exam and get the related certification.

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