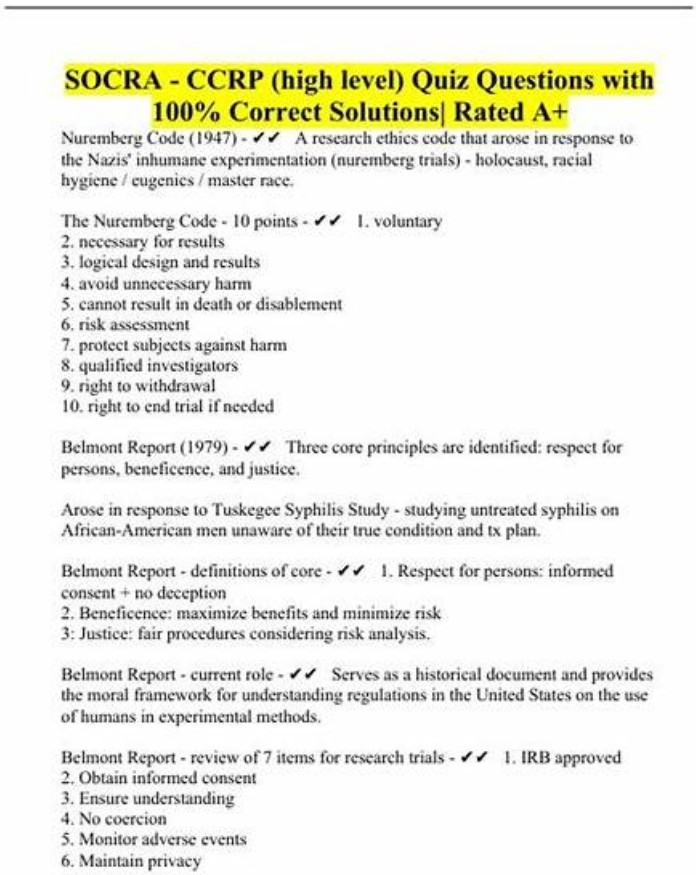
100% Pass Quiz 2026 SOCRA High Hit-Rate CCRP Clearer Explanation



SOCRA - CCRP (high level) Quiz Questions with 100% Correct Solutions| Rated A+

Nuremberg Code (1947) - ✔✔ A research ethics code that arose in response to the Nazis' inhumane experimentation (nuremberg trials) - holocaust, racial hygiene / eugenics / master race.

The Nuremberg Code - 10 points - ✔✔ 1. voluntary
2. necessary for results
3. logical design and results
4. avoid unnecessary harm
5. cannot result in death or disablement
6. risk assessment
7. protect subjects against harm
8. qualified investigators
9. right to withdrawal
10. right to end trial if needed

Belmont Report (1979) - ✔✔ Three core principles are identified: respect for persons, beneficence, and justice.

Arose in response to Tuskegee Syphilis Study - studying untreated syphilis on African-American men unaware of their true condition and tx plan.

Belmont Report - definitions of core - ✔✔ 1. Respect for persons: informed consent + no deception
2. Beneficence: maximize benefits and minimize risk
3: Justice: fair procedures considering risk analysis.

Belmont Report - current role - ✔✔ Serves as a historical document and provides the moral framework for understanding regulations in the United States on the use of humans in experimental methods.

Belmont Report - review of 7 items for research trials - ✔✔ 1. IRB approved
2. Obtain informed consent
3. Ensure understanding
4. No coercion
5. Monitor adverse events
6. Maintain privacy

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>> CCRP Clearer Explanation <<

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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 (Q83-Q88):

NEW QUESTION # 83
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. A change in the manufacturing site for the investigational product
- D. The addition of a sub-investigator with the scientific training and expertise to conduct the investigation

Answer: C

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 # 84
According to 21 CFR Part 11, each electronic signature must be unique and:

- A. Transferable to family
- B. Reassignable after validation
- C. Cannot be reused or reassigned
- D. Identical to handwritten signature

Answer: C

Explanation:
* 21 CFR 11.100(a):Requires that electronic signatures be "unique to one individual and shall not be reused or reassigned to anyone else."
* This ensures accountability and audit trail integrity.
References:21 CFR 11.100(a).

NEW QUESTION # 85
A nonrandomized study of 30 subjects entitled "A study to evaluate the effectiveness of and to determine the common short-term side effects associated with the drug 'PainStop' for the treatment of subjects with chronic arthritis" is an example of a:

- A. Phase II
- B. Phase I
- C. Phase III
- D. Phase IV

Answer: A

Explanation:
Phase classification is based on study objectives, not just subject numbers.
* Phase I:Focuses on safety, pharmacokinetics, dose-ranging, usually in healthy volunteers or small patient groups.
* Phase II:Evaluateseffectiveness in patients with the conditionand monitors common short-term side effects.
* Phase III:Confirms effectiveness in larger populations, compares to standard therapy, gathers more safety data.
* Phase IV:Post-marketing studies exploring new indications, long-term safety, or special populations.
The given study aims toevaluate effectiveness and common short-term side effectsin 30 arthritis patients, which clearly aligns withPhase IIobjectives. It is not exploratory safety (Phase I), not confirmatory comparative (Phase III), nor post-marketing (Phase IV).
Thus, the correct answer isB (Phase II).
References:
FDA Guidance: The IND Application - §312.21 (Phases of an investigation).
ICH E8(R1), General Considerations for Clinical Studies.

NEW QUESTION # 86
In accordance with the CFR, clinical trial sponsors are required to retain records and reports after a marketing application is approved for at least:

- A. 5 years
- B. 3 years
- C. 2 years
- D. 15 years

Answer: C

Explanation:
TheFDA record retention requirementfor investigational drug studies is clearly outlined in21 CFR 312.57 (c)and21 CFR 312.62(c).
* 21 CFR 312.57(c):"A sponsor shall retain the records and reports... for2 years after a marketing application is approvedfor the

drug; or, if an application is not approved, until 2 years after shipment and delivery of the drug for investigational use is discontinued and FDA has been so notified."
* 21 CFR 312.62(c):Investigators also must retain study-related records for2 years following the date a marketing application is approvedor 2 years after the investigation is discontinued.
This requirement ensures FDA can audit investigational product data even after approval to confirm compliance and verify trial results. Longer retention (e.g., 15 years) may be institutional or sponsor policy but is not mandated by federal law.
Thus, the correct answer isA (2 years).
References:
21 CFR 312.57(c) (Sponsor record retention).
21 CFR 312.62(c) (Investigator record retention).

NEW QUESTION # 87
In accordance with the CFR, the IRB/IEC membership must have:

- A. At least one individual who is not affiliated with the institution
- B. At least seven individuals
- C. At least one cleric
- D. A majority of individuals whose primary area of expertise is nonscientific

Answer: A

Explanation:
IRBs must be diverse and independent to protect human subjects.
* 21 CFR 56.107(d):"Each IRB shall include at least one member whose primary concerns are in nonscientific areas... andat least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person affiliated with the institution." There is no minimum requirement of seven members (A). Nonscientists must be represented but not a majority (B). Clergy are not mandated (C). The critical safeguard is inclusion of at leastone unaffiliated member (D)to ensure independence.
Thus, the correct answer isD (At least one unaffiliated individual).
References:
21 CFR 56.107(d) (IRB membership requirements).

NEW QUESTION # 88
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