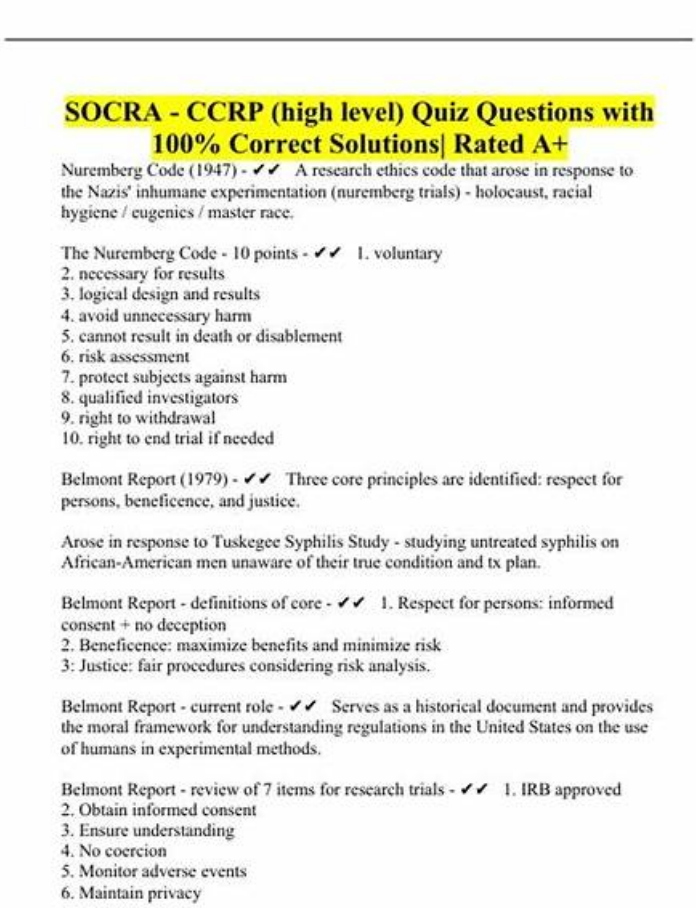
100% Pass Quiz SOCRA - CCRP - High Pass-Rate New Certified Clinical Research Professional (CCRP) Exam Practice



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Belmont Report - current role - ✔✔ Serves as a historical document and provides the moral framework for understanding regulations in the United States on the use of humans in experimental methods.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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In today's highly competitive SOCRA market, having the CCRP certification is essential to propel your career forward. To earn the SOCRA CCRP certification, you must successfully pass the CCRP Exam. However, preparing for the SOCRA CCRP exam can be challenging, with potential hurdles like exam anxiety and time constraints.

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.

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q44-Q49):

NEW QUESTION # 44
If a subject experiences a serious adverse event related to the study drug and only minimal information is available, the investigator must submit the information to the:

- A. Sponsor and IRB/IEC within seven days
- B. Sponsor and IRB/IEC immediately, then update later
- C. Sponsor and IRB/IEC within five days
- D. IRB/IEC immediately, then sponsor when full details are available

Answer: B

Explanation:
* ICH E6(R2) 4.11.1:Investigators must "immediately report all serious adverse events to the sponsor except for those the protocol identifies as not requiring immediate reporting."
* IRB must also be informed promptly per21 CFR 312.64(b).
* Follow-up information is submitted later as available.
References:ICH E6(R2), §4.11.1; 21 CFR 312.64(b).

NEW QUESTION # 45
Which document was created by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and summarizes the basic ethical principles and guidelines for the conduct of research involving human subjects?

- A. The Belmont Report
- B. The Nuremberg Code
- C. The Declaration of Helsinki
- D. The ICH Guidelines

Answer: A

Explanation:
TheBelmont Report (1979), issued by the U.S. National Commission, identifiesthree core ethical principles guiding human subject research:
* Respect for Persons(informed consent, autonomy, protection of vulnerable populations).
* Beneficence(maximize benefits, minimize harms).
* Justice(fairness in subject selection and treatment).
* TheNuremberg Code (1947)was developed post-WWII to prevent unethical experiments.
* TheDeclaration of Helsinki (1964, updated)is a World Medical Association document guiding international physician research ethics.
* TheICH Guidelines (1996)outline harmonized regulatory requirements for good clinical practice.
Only the Belmont Report fits the description of a U.S.-based, principle-driven framework for human research ethics.
Thus, the correct answer isD (The Belmont Report).
References:
The Belmont Report (1979), National Commission for the Protection of Human Subjects.
45 CFR 46 (Human Subject Protections).

NEW QUESTION # 46
While reviewing site records during a monitoring visit, a monitor can cite which of the following as a site violation of informed consent regulations?

- A. Only the signatures of the person obtaining consent and the witness appear on the copy of the summary of the short form consent
- B. A subject's signature is missing on the copy of the summary of the short form consent
- C. The sponsor-generated informed consent template is missing required elements
- D. A copy of the consent document was not provided to a subject

Answer: D

Explanation:
Providing acopy of the signed consent formto subjects is a mandatory requirement.
* 21 CFR 50.27(a):"A copy shall be given to the person signing the form."
* ICH E6(R2) 4.8.11:Reinforces that "a copy of the signed and dated written informed consent form should be given to the subject."
Failure to provide this copy constitutes adirect violation of informed consent regulations.
Other issues:
* A & C concern proper short form process but do not invalidate informed consent if a copy was provided.
* D concerns sponsor template, but the site's responsibility is ensuring use of IRB-approved version.
Correct answer:B.
References:
21 CFR 50.27(a).
ICH E6(R2), §4.8.11.

NEW QUESTION # 47
Sponsor must maintain drug disposition records for how long after marketing approval?

- A. 3 years
- B. 2 years
- C. 5 years
- D. 1 year

Answer: B

Explanation:
* 21 CFR 312.57(c):"Sponsors shall retain records for2 years after a marketing application is approvedor if not approved, 2 years after shipment and delivery of investigational drug for investigation." References:21 CFR 312.57(c).

NEW QUESTION # 48
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 - particularlytemperature 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 isC (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 # 49
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