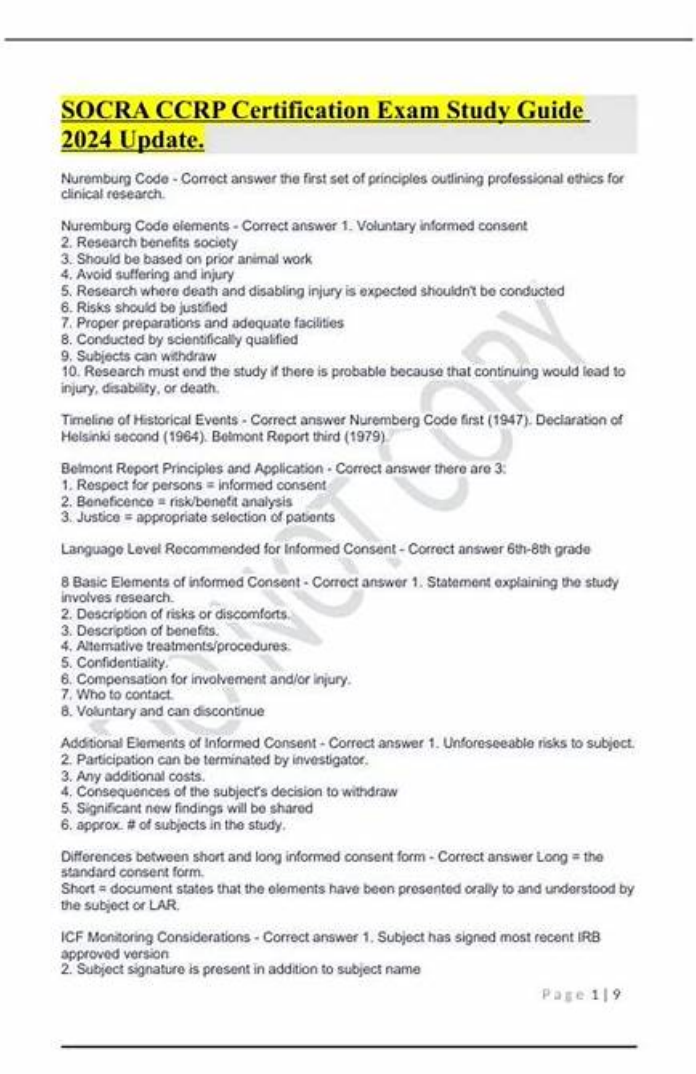
SOCRA CCRP Exam Demo | Latest CCRP Exam Camp



SOCRA CCRP Certification Exam Study Guide 2024 Update.

Nuremburg Code - Correct answer the first set of principles outlining professional ethics for clinical research.

Nuremburg Code elements - Correct answer 1. Voluntary informed consent
2. Research benefits society
3. Should be based on prior animal work
4. Avoid suffering and injury
5. Research where death and disabling injury is expected shouldn't be conducted
6. Risks should be justified
7. Proper preparations and adequate facilities
8. Conducted by scientifically qualified
9. Subjects can withdraw
10. Research must end the study if there is probable because that continuing would lead to injury, disability, or death.

Timeline of Historical Events - Correct answer Nuremberg Code first (1947). Declaration of Helsinki second (1964). Belmont Report third (1979).

Belmont Report Principles and Application - Correct answer there are 3:
1. Respect for persons = informed consent
2. Beneficence = risk/benefit analysis
3. Justice = appropriate selection of patients

Language Level Recommended for Informed Consent - Correct answer 6th-8th grade

8 Basic Elements of informed Consent - Correct answer 1. Statement explaining the study involves research.
2. Description of risks or discomforts.
3. Description of benefits.
4. Alternative treatments/procedures.
5. Confidentiality.
6. Compensation for involvement and/or injury.
7. Who to contact.
8. Voluntary and can discontinue

Additional Elements of Informed Consent - Correct answer 1. Unforeseeable risks to subject.
2. Participation can be terminated by investigator.
3. Any additional costs.
4. Consequences of the subject's decision to withdraw
5. Significant new findings will be shared
6. approx. # of subjects in the study.

Differences between short and long informed consent form - Correct answer Long = the standard consent form.
Short = document states that the elements have been presented orally to and understood by the subject or LAR.

ICF Monitoring Considerations - Correct answer 1. Subject has signed most recent IRB approved version
2. Subject signature is present in addition to subject name

Page 1 | 9

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SOCRA CCRP Exam Syllabus Topics:

Topic	Details
Topic 1	• 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.

Topic 2	• 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.

2025 SOCRA CCRP: Professional Certified Clinical Research Professional (CCRP) Exam Demo

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q110-Q115):

NEW QUESTION # 110
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 # 111
After completion of a Phase III trial, which document should IRB/IEC retain?

- A. Investigational product labels
- B. Sponsor/investigator contracts
- C. Subject enrollment logs
- D. Occupations and affiliations of IRB members

Answer: D

Explanation:
* 21 CFR 56.115(a)(5):IRBs must retain records of IRB membership (names, qualifications, affiliations, occupations).
* Other documents (contracts, enrollment logs, product labels) are site or sponsor responsibilities, not IRB's.
References:21 CFR 56.115(a)(5).

NEW QUESTION # 112
A subject on a multi-drug regimen could not tolerate a non-investigational drug. Can the investigational regimen continue?

- A. Only after sponsor and IRB approval
- B. Only for a short time, then change to placebo
- C. Only after medical monitor approval
- D. Yes, per protocol

Answer: A

Explanation:
* ICH E6(R2) 4.5.1:Investigators must follow the protocol approved by the IRB/IEC.
* Any modification that is not pre-specified must be approved by sponsor and IRB before continuing.
Only deviations eliminating immediate hazard can be done without prior approval; in this case, continuation requires sponsor + IRB agreement.
References:ICH E6(R2) §4.5.1.

NEW QUESTION # 113
According to the CFR and the ICH GCP Guideline, which of the following must be submitted to the IRB after completion of the trial at the site?

- A. The final report
- B. The final subject enrollment log
- C. The data safety monitoring summary
- D. The monitoring close-out visit report

Answer: A

Explanation:
When a trial ends at a site, the investigator has an obligation to submit a final report to the IRB/IEC. This is outlined in both ICH and CFR:
ICH E6(R2) 4.13: "Upon completion of the trial, the investigator should provide the IRB/IEC with a summary of the trial's outcome."
21 CFR 312.66: Requires investigators to "report to the IRB all changes in the research activity and all unanticipated problems involving risk, and to provide reports at the end of the study." The final report provides closure and documentation that the study was conducted ethically and in compliance with regulatory standards. Other documents listed in the options (monitoring reports, DSMB summaries, subject logs) may be retained by the sponsor or site, but they are not mandated for IRB submission.
Thus, the correct answer is A (Final Report). This ensures the IRB/IEC has an accurate record of study completion, outcome, and compliance with ethical oversight.
References:
ICH E6(R2), §4.13 (Final reporting to IRB/IEC).
21 CFR 312.66 (IRB review and reporting).

NEW QUESTION # 114
An investigator reports a serious adverse event suspected to be drug-related. By CFR, the sponsor must notify FDA no later than:

- A. 1 day
- B. 15 days
- C. 7 days
- D. 10 days

Answer: C

Explanation:

* 21 CFR 312.32(c)(2):Life-threatening or fatal unexpected adverse events must be reported within7 calendar days.Other serious unexpected events are reported within 15 days.
References:21 CFR 312.32(c)(2).

NEW QUESTION # 115
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