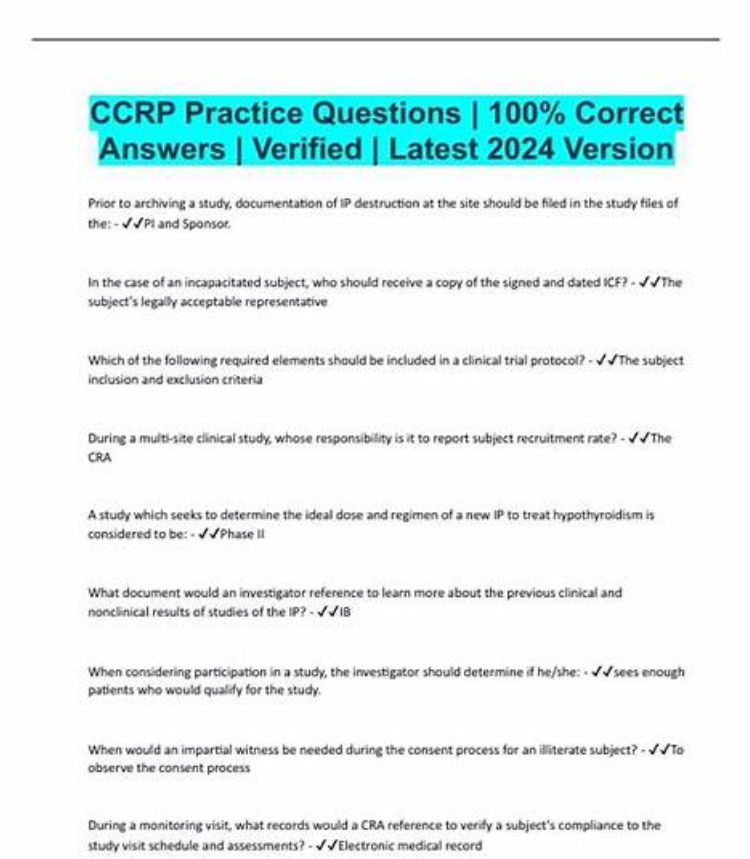
Test CCRP Lab Questions, CCRP Interactive Course



CCRP Practice Questions | 100% Correct Answers | Verified | Latest 2024 Version

Prior to archiving a study, documentation of IP destruction at the site should be filed in the study files of the: - ✓✓PI and Sponsor.

In the case of an incapacitated subject, who should receive a copy of the signed and dated ICF? - ✓✓The subject's legally acceptable representative

Which of the following required elements should be included in a clinical trial protocol? - ✓✓The subject inclusion and exclusion criteria

During a multi-site clinical study, whose responsibility is it to report subject recruitment rate? - ✓✓The CRA

A study which seeks to determine the ideal dose and regimen of a new IP to treat hypothyroidism is considered to be: - ✓✓Phase II

What document would an investigator reference to learn more about the previous clinical and nonclinical results of studies of the IP? - ✓✓IB

When considering participation in a study, the investigator should determine if he/she: - ✓✓sees enough patients who would qualify for the study.

When would an impartial witness be needed during the consent process for an illiterate subject? - ✓✓To observe the consent process

During a monitoring visit, what records would a CRA reference to verify a subject's compliance to the study visit schedule and assessments? - ✓✓Electronic medical record

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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.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q14-Q19):

NEW QUESTION # 14
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. Storage facility temperature range
- B. Number of staff members
- C. Available storage square footage
- D. Storage cost

Answer: A

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 # 15
A research site was invited to participate in an investigational drug study. Which of the following parties is responsible for determining the risk-benefit ratio at the site?

- A. The sponsor
- B. The site's legal counsel
- C. The IRB/IEC
- D. The clinical investigator

Answer: C

Explanation:
Therisk-benefit ratiois a core responsibility of the IRB/IEC.
* 21 CFR 56.111(a)(2):"Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result."
* ICH E6(R2) 3.1.2:IRB/IEC must safeguard rights, safety, and well-being of subjects, with special attention to risk-benefit evaluation.
Investigators (A) provide medical judgment but do not formally approve the risk-benefit balance. Sponsors (D) design studies but must submit to IRB for independent review. Legal counsel (C) is not part of the scientific/ethical evaluation.
Thus,IRB/IEC is directly responsible for approving the risk-benefit ratio.
References:
21 CFR 56.111(a)(2).
ICH E6(R2), §3.1.2.

NEW QUESTION # 16
In accordance with 21 CFR Part 11, a closed electronic records system must do all EXCEPT:

- A. Maintain accurate records throughout retention
- B. Customize access rights
- C. Generate audit trails
- D. Print a complete paper copy

Answer: D

Explanation:
* 21 CFR 11.10:Requires validation, audit trails, secure access, but does not mandate printing capability.
Thus, (D) is the exception.
References:21 CFR 11.10.

NEW QUESTION # 17
Which document was created as a response to unethical WWII human experiments?

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

Answer: C

Explanation:
* TheNuremberg 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 isthe Nuremberg Code.
References:Nuremberg Code, 1947.

NEW QUESTION # 18
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. Sub-investigators
- B. Participants in long-term follow-up
- C. The IRB/IEC
- D. No notification is required

Answer: C

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 # 19
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