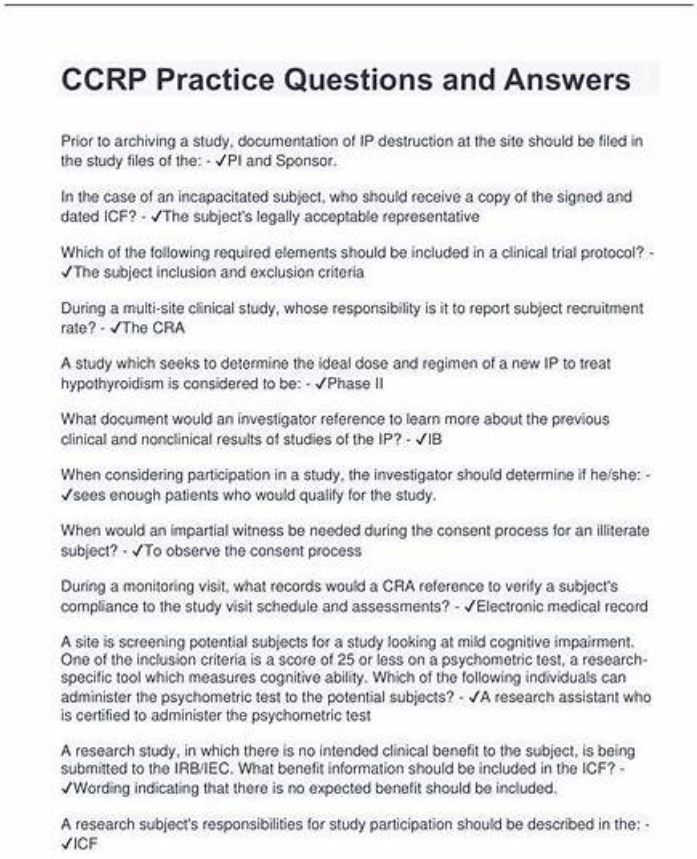
Latest CCRP Practice Questions - CCRP Valid Exam Prep



CCRP Practice Questions and Answers

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

A site is screening potential subjects for a study looking at mild cognitive impairment. One of the inclusion criteria is a score of 25 or less on a psychometric test, a research-specific tool which measures cognitive ability. Which of the following individuals can administer the psychometric test to the potential subjects? - ✓A research assistant who is certified to administer the psychometric test

A research study, in which there is no intended clinical benefit to the subject, is being submitted to the IRB/IEC. What benefit information should be included in the ICF? - ✓Wording indicating that there is no expected benefit should be included.

A research subject's responsibilities for study participation should be described in the: - ✓ICF

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What is more difficult is not only passing the SOCRA CCRP Certification Exam, but the acute anxiety and the excessive burden also make the candidate nervous to qualify for the Certified Clinical Research Professional (CCRP) certification. If you are going through the same tough challenge, do not worry because SOCRA is here to assist you.

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.

CCRP Valid Exam Prep, CCRP Exam Flashcards

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SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q131-Q136):

NEW QUESTION # 131
A revised protocol added genomic testing to banked tissue samples. Before shipping samples, what must the site do?

- A. Execute material transfer agreement
- B. Ship under dangerous goods requirements
- C. Notify enrolled subjects
- D. Obtain IRB/IEC approval for revised protocol and ICF

Answer: D

Explanation:
* 21 CFR 56.109(a):IRB must review and approve any protocol amendments before implementation.
* ICH E6(R2) 4.5.2:Changes affecting subjects (e.g., genomic testing) require IRB/IEC approval and updated consent.
Thus, site must first obtainIRB approval for revised protocol and ICF.
References:21 CFR 56.109(a); ICH E6(R2) §4.5.2.

NEW QUESTION # 132
For a study with a significant risk investigational medical device that could optimize the effects of radiation therapy on cancer tumors, the investigational plan states mild burns are an anticipated effect. One subject developed severe burns with blistering. In accordance with the CFR, this effect must be reported to the sponsor and the IRB/IEC as soon as possible and at most how long after the investigator first learns of the effect?

- A. 2 working days
- B. 5 working days
- C. 7 working days
- D. 10 working days

Answer: D

Explanation:
In device trials,unanticipated adverse device effects (UADEs)must be promptly reported.
* 21 CFR 812.150(a)(1):"An investigator shall submit to the sponsor and the reviewing IRB a report of anyunanticipated adverse device effectas soon as possible, but in no event later than10 working days after the investigator first learns of the effect." In this case,severe burns with blisteringgo beyond the anticipated effect of mild burns listed in the investigational plan. Therefore, it qualifies as aUADEand triggers expedited reporting. Options A, B, and C are too short; the regulation specifically mandates a10 working day maximumtimeframe.
Thus, the correct answer isD (10 working days).
References:
21 CFR 812.150(a)(1) (Reporting requirements for investigators).

NEW QUESTION # 133
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. 2 years
- B. 5 years
- C. 15 years
- D. 3 years

Answer: A

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 # 134
In order to meet recruitment goals, a sponsor is adding a new site to a multi-center study. Which of the following documents should the sponsor obtain from a new site prior to starting research at the site?

- A. The IRB/IEC trial approval documentation
- B. The site's accreditation certificate
- C. The delegation of duties log
- D. The site's SOPs

Answer: A

Explanation:
* ICH E6(R2) 4.4.1:"Before initiating a trial, the investigator/institution should have written and dated approval/favorable opinion from the IRB/IEC."
* Sponsors must confirm IRB approval before authorizing initiation.
References:ICH E6(R2), §4.4.1.

NEW QUESTION # 135
A study subject in a double-blinded, placebo-controlled Phase III study experienced a serious adverse event that could be related to

the study drug. The clinical investigator is out of town, and the sub-investigator needs to break the blind. Where can the sub-investigator find a description of the unblinding procedure?

- A. The study protocol
- B. The Investigator's Brochure
- C. The case report form
- D. The informed consent form

Answer: A

Explanation:
Unblinding procedures are aprotocol-level responsibilitybecause they involve trial design, safety management, and subject protection.
* ICH E6(R2) 6.0 (Protocol and amendments):Requires the protocol to specify "the treatment(s) and treatment periods, procedures for randomization and blinding, andprocedures for breaking codes."
* ICH E6(R2) 4.7:"The investigator should follow the trial's randomization procedure, if any, and should ensure that the code is broken only in accordance with the protocol." The informed consent (A) explains risks and rights but does not include operational unblinding procedures.
The Investigator's Brochure (B) summarizes preclinical/clinical data but does not dictate site-specific trial management. The CRF (D) is for data capture and has no procedural detail.
Therefore, the correct answer isC (The study protocol), as it outlines unblinding steps and documentation requirements.
References:
ICH E6(R2), §6.0 (Protocol content).
ICH E6(R2), §4.7 (Randomization and unblinding).

NEW QUESTION # 136
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