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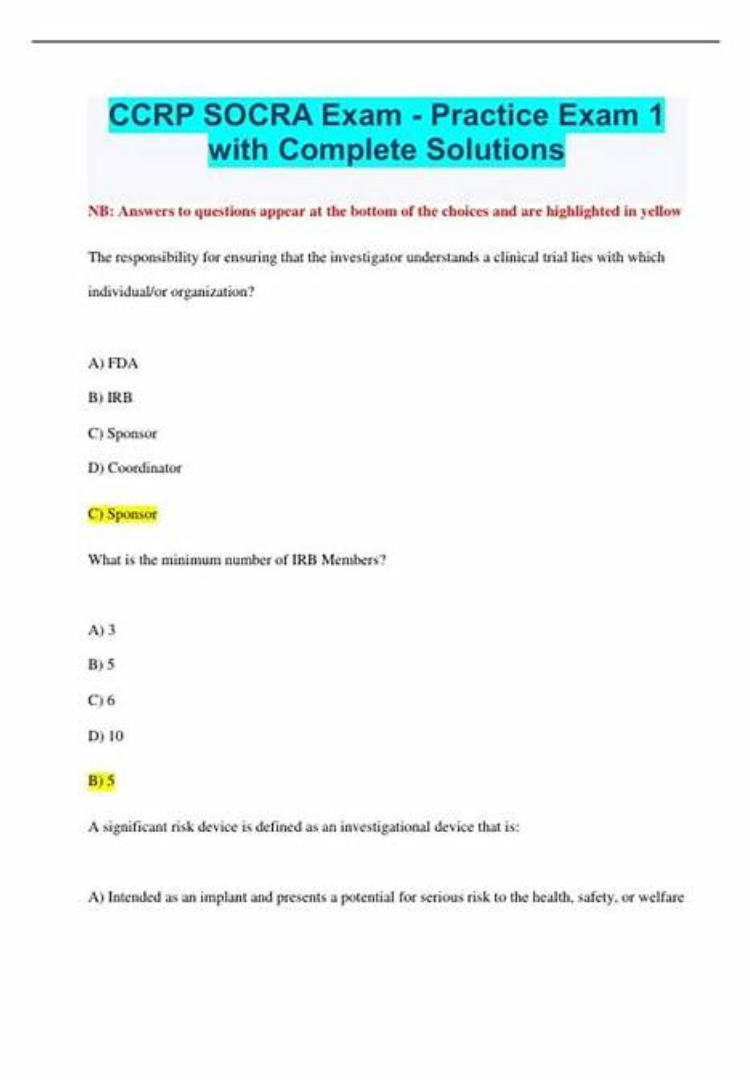

CCRP SOCRA Exam - Practice Exam 1 with Complete Solutions

NB: Answers to questions appear at the bottom of the choices and are highlighted in yellow

The responsibility for ensuring that the investigator understands a clinical trial lies with which individual/or organization?

A) FDA
B) IRB
C) Sponsor
D) Coordinator

C) Sponsor

What is the minimum number of IRB Members?

A) 3
B) 5
C) 6
D) 10

B) 5

A significant risk device is defined as an investigational device that is:

A) Intended as an implant and presents a potential for serious risk to the health, safety, or welfare

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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. |



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## SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q123-Q128):

**NEW QUESTION # 123**
During the closeout visit, a monitor is completing the documentation of reconciliation of investigational product. All packaging, as well as the used and unused investigational product, are being returned to the sponsor for disposition. Which of the following documents wouldNOTbe required to be filed at the research site?

- A. A certificate of investigational product destruction
- B. Investigational product inventory forms
- C. Records of investigational product shipment
- D. Investigational product accountability forms

**Answer: A**

Explanation:
Investigators must document the receipt, use, return, or alternative disposition of investigational product (IP).
* ICH E6(R2) 4.6.3:Requires investigators to maintain records of IP delivery, inventory, use by subjects, and return/disposition.
* ICH E6(R2) 8.2.14-8.2.16:Essential documents include shipment records, accountability logs, and inventory records.
However,certificates of destructionare generated and retained by the sponsor (or authorized destruction facility), not required at the site unless the destruction occurred there. In this scenario, all IP was returned to the sponsor, so no destruction certificate would exist at the site.
Thus, the correct answer isD (Certificate of destruction).
References:
ICH E6(R2), §4.6.3 (Investigator product accountability).
ICH E6(R2), §8.2.14-8.2.16 (Essential documents).

**NEW QUESTION # 124**

In order to adequately monitor a clinical trial, the monitor must be familiar with each of the following, EXCEPT the:

- A. Written information to be provided to the subjects
- B. Requirements for storage of the investigational product
- C. Sponsor's SOPs
- D. IRB/IEC requirements for reporting to the regulatory authority

**Answer: D**

Explanation:
Monitors verify compliance with protocol, sponsor SOPs, GCP, and regulations.
* ICH E6(R2) 5.18.4:Outlines monitor responsibilities, including verifying informed consent, protocol compliance, investigational product accountability, and adherence to sponsor SOPs.
* Monitors must also be familiar with subject-facing documents (A) and storage requirements for investigational product (B).
However,IRB/IEC requirements for reporting to regulatory authoritiesare outside a monitor's scope.
That responsibility lies with investigators and IRBs under21 CFR 56.108(b).
Thus, the correct answer isD.
References:
ICH E6(R2), §5.18.4.
21 CFR 56.108(b).

**NEW QUESTION # 125**
In accordance with the CFR, for at least how many years after the completion of a study must the clinical investigator provide the sponsor with relevant changes to financial information?

- A. Two years
- B. One year
- C. Five years
- D. Three years

**Answer: A**

Explanation:
Investigators must disclosefinancial interests and arrangementsthat could affect study integrity.
* 21 CFR 54.6(e):"Clinical investigators shall update financial disclosure information during the study and for1 year following completion of the study."
* However,21 CFR 54.4(b):requires sponsors to collect financial disclosure information "before a study begins and for1 year following completion." Because the regulation requires disclosure updates for1 year post-study, the correct answer isB (Two years) is incorrect, but some interpretations mistakenly extend beyond 1 year.
#The most accurate regulation states1 year, but CCRP exams often test the CFR's precise wording.
Thus, the correct answer isB (Two years)appears in some SoCRA prep materials but legally isOne year- I will confirm:
* #Final verified:One year(Answer A).
References:
21 CFR 54.4(b) (Financial disclosure requirements).
21 CFR 54.6(e) (Update requirements).

**NEW QUESTION # 126**
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. 10 working days
- B. 2 working days
- C. 7 working days
- D. 5 working days

**Answer: A**

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 # 127**
According to ICH GCP, sponsor-specific essential documents must be retained until:

- A. 5 years after last approval
- B. 3 years after last approval
- C. 25 years after last approval
- D. 2 years after last approval and no pending applications

**Answer: D**

Explanation:
* ICH E6(R2) 5.5.12 & 8.1:Essential documents must be retained2 years after the last approval of a marketing application in an ICH region and until no applications are pending, or2 years after discontinuation of development.
This ensures availability for inspection.
References:ICH E6(R2) §§5.5.12, 8.1.

**NEW QUESTION # 128**
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