Certification CCRP Questions | CCRP Exam Objectives

SOCRA (CCRP) certification Exam Practice Questions with Answers

The Belmont Report's principle of respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that: -
✔Persons with diminished autonomy are entitled to protection.

Which of the following is an example of how the principle of beneficence can be applied to a study employing human subjects? -
✔Determining that the study has a maximization of benefits and a minimization of risks.

Which of the following are the three principles discussed in the Belmont Report? -
✔Respect for Persons, Beneficence, Justice

The principle of justice in the Belmont report relates to -
✔Distributions of burdens and benefits

Respects for person in the Belmont report relates to -
✔Decision on the part of subjects to voluntarily participate or not in research (Informed consent and Privacy)

Which of the following is cited as an influence in the Belmont report? -
✔Nuremberg war crime trial involving Nazi medical experiments

Which of the following is cited in the principle of justice as exemplifying an injustice? -
✔Tuskegee Study

The Commission that formulated the Belmont report was created as part of -
✔National Commission of 1979

The Belmont report was formulated by -
✔National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

The Belmont report addresses -
✔Differences between practice and research

The IRB should refer to the principle of beneficence in the Belmont report when it is evaluating -
✔Risk benefit ratio

The candidates can test themselves for the Certified Clinical Research Professional (CCRP) exam day by attempting the Certified Clinical Research Professional (CCRP) CCRP practice test on the software. There is preparation material available on the CCRP Practice Exam software by TestsDumps to study for the SOCRA CCRP test.

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 (Q66-Q71):

NEW QUESTION # 66
In accordance with the ICH GCP Guideline, when a sponsor transfers trial-related duties andfunctions to a contract research organization (CRO), who is ultimately responsible for the quality and integrity of the trial data?

- A. The investigator
- B. The IRB/IEC
- C. The sponsor
- D. The CRO

Answer: C

Explanation:
Outsourcing does not shift ultimate responsibility away from the sponsor. Exact extract:
* ICH E6(R2) 5.2.1: "A sponsor may transfer any or all of the sponsor's trial-related duties... to a CRO, but the ultimate responsibility for the quality and integrity of the trial data always resides with the sponsor."Hence, D is correct.
References:
ICH E6(R2) Good Clinical Practice, §5.2.1 (Sponsor/CRO).==========

NEW QUESTION # 67
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. IRB/IEC immediately, then sponsor when full details are available
- B. Sponsor and IRB/IEC within five days
- C. Sponsor and IRB/IEC immediately, then update later
- D. Sponsor and IRB/IEC within seven days

Answer: C

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 # 68
A sponsor became aware of a new serious adverse event related to a drug. Who must be notified in addition to FDA?

- A. All investigational pharmacists
- B. All IRBs/IECs of record
- C. All participating investigators
- D. OHRP

Answer: C

Explanation:
* 21 CFR 312.32(c)(1)(ii):Sponsors must notifyall participating investigatorsof any serious and unexpected suspected adverse reactions.
* Investigators then inform IRBs and subjects as appropriate.
References:21 CFR 312.32(c)(1)(ii).

NEW QUESTION # 69
A monitor is conducting a site closeout visit. The study site kept electronic medical records and source documents in a system verified to be 21 CFR Part 11 compliant. The monitor reviewed all electronic documents by logging into the system with a unique login ID and password. In addition to the essential document file, which of the following sets of documents should be provided to the monitor during the study closeout visit?

- A. Informed consent documents and printouts of electronic source documents
- B. Printouts of electronic source documents and the remaining investigational product
- C. Informed consent documents and investigational product documentation
- D. A copy of the final report for the IRB and investigational product shipment records

Answer: C

Explanation:
During study closeout, the monitor verifies subject protection, protocol compliance, and investigational product accountability.
* ICH E6(R2) 8.1 & 8.4:Lists essential documents to be verified at closeout, including signed informed consent forms and investigational product accountability records.
* 21 CFR Part 11:Ensures electronic records are valid, so printed copies are not always necessary unless required for auditing.
Thus, the critical items for monitor review at closeout areinformed consent forms(to confirm subject protection) andinvestigational product documentation(to confirm reconciliation and disposition).
Correct answer:D.
References:
ICH E6(R2), §8.1, §8.4.

NEW QUESTION # 70
An investigator is working with a new sponsor to submit a cardiovascular trial to the IRB/IEC. In accordance with the ICH GCP

Guidelines, which parties should sign the protocol to confirm agreement that the trial will be conducted as agreed?

- A. The investigator/institution and the delegated site staff
- B. The investigator/institution and the sponsor
- C. The sponsor and the FDA
- D. The sponsor and the IRB/IEC

Answer: B

Explanation:
Theprotocol signature pagedocuments agreement between the sponsor and the investigator/institution to conduct the trial in compliance with ICH GCP, the protocol, and regulatory standards.
* ICH E6(R2) 8.2.2 (Signed protocol and amendments):Requires "the sponsor and investigator /institution to sign the protocol and amendments, confirming agreement."
* ICH E6(R2) 4.5.1:"The investigator should conduct the trial in compliance with the protocol agreed to by the sponsor and, if required, approved by the regulatory authority(ies) and by the IRB/IEC." The sponsor-investigator signatures ensure shared accountability for subject protection, data integrity, and adherence to trial methodology. Neither delegated staff (B) nor IRB/IEC (C) nor FDA (D) sign protocols.
These bodies approve or oversee, but do not formally enter into execution of the protocol.
Thus, the correct answer isA (The investigator/institution and the sponsor).
References:
ICH E6(R2), §8.2.2 (Signed protocol and amendments).
ICH E6(R2), §4.5.1 (Investigator compliance with protocol).

NEW QUESTION # 71
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