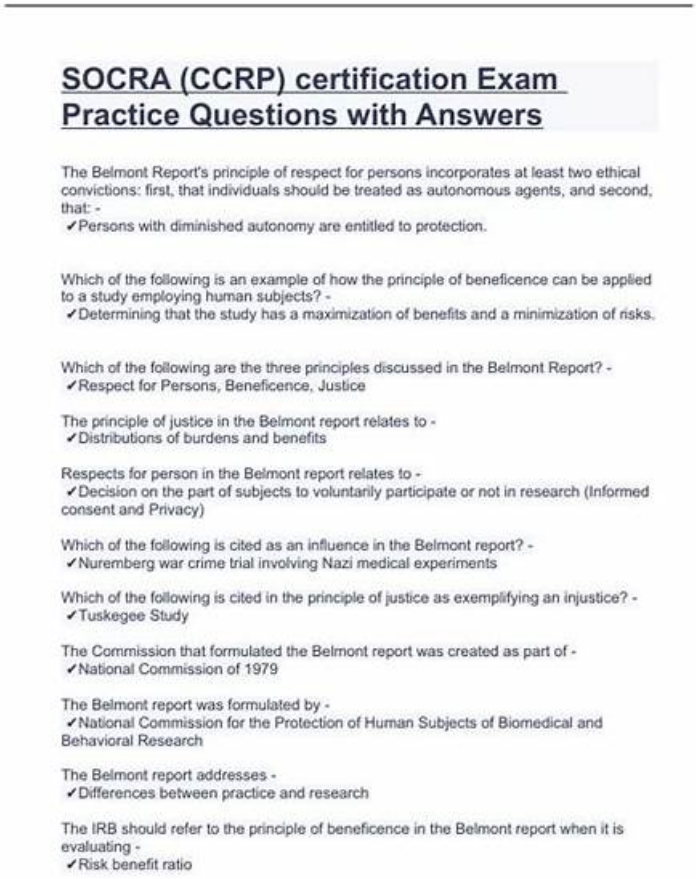
# Free PDF Quiz 2026 SOCRA CCRP: Certified Clinical Research Professional (CCRP)–Valid Latest Test Guide



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

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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 (Q37-Q42):

**NEW QUESTION # 37**
A clinical investigator received an honorarium from the sponsor of a covered study. At what payment value must this be reported?

- A. >$25,000
- B. $5,000
- C. $10,000
- D. Any amount

**Answer: C**

Explanation:
* 21 CFR 54.2(f) & 54.4(a):Requires disclosure of "significant payments of other sorts" (SPOOS) that exceed$25,000or equity interests exceeding$50,000.
* However,honoraria or consulting exceeding $10,000 annuallyalso trigger disclosure.
Thus, the reporting threshold is$10,000.
References:21 CFR 54.2(f), 54.4(a).

**NEW QUESTION # 38**
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 # 39**
In accordance with the ICH GCP Guideline, which of the following can an Independent Data Monitoring Committee provide?

- A. The selection of qualified investigators
- B. An initial review and approval of a trial
- C. Suggestions for a new trial design
- D. Recommendations to stop a trial

**Answer: D**

Explanation:
AnIndependent Data Monitoring Committee (IDMC or DSMB)is a group of independent experts established to review accumulating safety and efficacy data during a trial. Their main role is to ensure subject protection and trial integrity.
* ICH E6(R2) 5.5.1:"The sponsor may consider establishing anindependent data-monitoring committee (IDMC)to assess the progress of a clinical trial, including the safety data and the critical efficacy endpoints, and to recommend to the sponsor whether to continue, modify, or stop a trial." Thus, DSMBs/IDMCsdo not perform trial approvals (A),do not design trials (C), anddo not select investigators (D). Their authority is strictly advisory, providing recommendations to sponsors about safety and whether continuation of the study is ethically justified. The sponsor makes the final decision, but DSMB recommendations are highly influential.
Therefore, the correct answer isB (Recommendations to stop a trial).
References:
ICH E6(R2), §5.5.1 (Independent Data Monitoring Committees).

**NEW QUESTION # 40**
In a Phase III cardiovascular trial, who is responsible for ongoing clinical trial safety evaluation?

- A. FDA
- B. Sponsor
- C. IRB/IEC
- D. Pharmacist

**Answer: B**

Explanation:
* ICH E6(R2) 5.16:Sponsors must implement ongoing safety evaluation, including expedited and periodic reporting.FDA and IRB review but do not conduct active monitoring.
References:ICH E6(R2), §5.16.

**NEW QUESTION # 41**
In a completed multi-site Phase I drug study using remote EDC, who ensures the system complies with accuracy and reliability requirements?

- A. Institution

- B. Regulatory authority
- C. Sponsor
- D. Investigator

**Answer: C**

Explanation:
* ICH E6(R2) 5.5.3:Sponsors are responsible for validating computerized systems used in trials.
Investigators ensure proper data entry, but system compliance lies with sponsor.
References:ICH E6(R2), §5.5.3.

**NEW QUESTION # 42**
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