

CCRP시험대비공부하기 - CCRP시험준비공부



참고: Itcertkr에서 Google Drive로 공유하는 무료 2025 SOCRA CCRP 시험 문제집이 있습니다:
<https://drive.google.com/open?id=18EusFpQOp09O46xpYsw8NvyS0xG1QKmi>

Itcertkr는 응시자에게 있어서 시간이 정말 소중한다는 것을 잘 알고 있으므로 SOCRA CCRP덤프를 자주 업데이트 하고, 오래 되고 더 이상 사용 하지 않는 문제들은 바로 삭제해버리며 새로운 최신 문제들을 추가 합니다. 이는 응 시자가 확실하고도 빠르게SOCRA CCRP덤프를 마스터하고SOCRA CCRP시험을 패스할수 있도록 하는 또 하나의 보장입니다.

SOCRA CCRP 시험요강:

주제	소개
주제 1	<ul style="list-style-type: none">• 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.
주제 2	<ul style="list-style-type: none">• 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.

>> CCRP시험대비 공부하기 <<

시험대비 CCRP시험대비 공부하기 최신버전 덤프샘플 문제

Itcertkr에서는 IT인증시험에 대비한 퍼펙트한SOCRA 인증CCRP덤프를 제공해드립니다. 시험공부할 시간이 충족

하지 않은 분들은 Itcertkr 에서 제공해드리는 SOCRA 인증 CCRP 덤프로 시험준비를 하시면 자격증 취득이 쉬워집니다. 덤프를 구매하시면 일년무료 업데이트서비스도 받을 수 있습니다.

최신 Clinical Research Professional CCRP 무료샘플문제 (Q73-Q78):

질문 # 73

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

정답: C

설명:

* 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.

질문 # 74

An investigator received \$60,000 equity interest three years after study completion. What is the financial reporting requirement?

- A. None
- B. Report to FDA
- C. Report to OHRP
- D. Report to sponsor

정답: A

설명:

* 21 CFR 54.4(b): Requires disclosure during the study and for 1 year after completion.

* After three years, no disclosure is required.

References: 21 CFR 54.4(b).

질문 # 75

Which document was created by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and summarizes the basic ethical principles and guidelines for the conduct of research involving human subjects?

- A. The Belmont Report
- B. The ICH Guidelines
- C. The Nuremberg Code
- D. The Declaration of Helsinki

정답: A

설명:

The Belmont Report (1979), issued by the U.S. National Commission, identifies three core ethical principles guiding human subject research:

* Respect for Persons (informed consent, autonomy, protection of vulnerable populations).

* Beneficence (maximize benefits, minimize harms).

* Justice (fairness in subject selection and treatment).

* The Nuremberg Code (1947) was developed post-WWII to prevent unethical experiments.

* The Declaration of Helsinki (1964, updated) is a World Medical Association document guiding international physician research ethics.

* The ICH Guidelines (1996) outline harmonized regulatory requirements for good clinical practice.
Only the Belmont Report fits the description of a U.S.-based, principle-driven framework for human research ethics.
Thus, the correct answer is D (The Belmont Report).
References:
The Belmont Report (1979), National Commission for the Protection of Human Subjects.
45 CFR 46 (Human Subject Protections).

질문 # 76

In accordance with the ICH GCP Guideline, who is responsible for the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor in the case report forms and in all required reports?

- A. The contract research organization monitor
- B. The quality control specialist
- C. The clinical investigator
- D. The IRB/IEC coordinator

정답: C

설명:

The investigator holds ultimate responsibility for all data reported.

* ICH E6(R2) 4.9.1: "The investigator is responsible for the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor on the CRFs and all required reports."

* Monitors (D) verify data accuracy but are not responsible for data quality. Quality specialists (B) and IRB staff (C) have no role in data entry.

Correct answer: A (The clinical investigator).

References:

ICH E6(R2), §4.9.1.

질문 # 77

A subject on a multi-drug regimen could not tolerate a non-investigational drug. Can the investigational regimen continue?

- A. Yes, per protocol
- B. Only after medical monitor approval
- C. Only for a short time, then change to placebo
- D. Only after sponsor and IRB approval

정답: D

설명:

* ICH E6(R2) 4.5.1: Investigators must follow the protocol approved by the IRB/IEC.

* Any modification that is not pre-specified must be approved by sponsor and IRB before continuing.

Only deviations eliminating immediate hazard can be done without prior approval; in this case, continuation requires sponsor + IRB agreement.

References: ICH E6(R2) §4.5.1.

질문 # 78

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SOCRA CCRP 시험이 어렵다고 해도 Itcertkr의 SOCRA CCRP 시험잡이 덤프가 있는 한 아무리 어려운 시험이라도 쉬워집니다. 어려운 시험이라 막무가내로 시험준비하지 마시고 문항수도 적고 모든 시험문제를 커버할 수 있는 SOCRA CCRP 자료로 대비하세요. 가장 적은 투자로 가장 큰 득을 보실 수 있습니다.

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