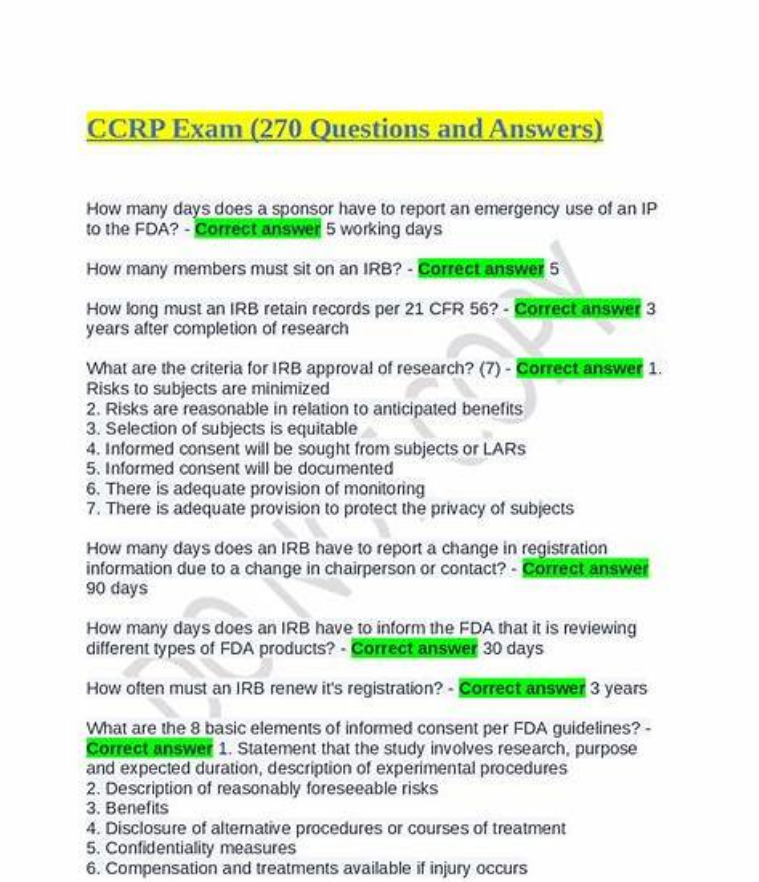
Sample CCRP Questions Answers | Real CCRP Dumps



CCRP Exam (270 Questions and Answers)

How many days does a sponsor have to report an emergency use of an IP to the FDA? - Correct answer 5 working days

How many members must sit on an IRB? - Correct answer 5

How long must an IRB retain records per 21 CFR 56? - Correct answer 3 years after completion of research

What are the criteria for IRB approval of research? (7) - Correct answer 1. Risks to subjects are minimized
2. Risks are reasonable in relation to anticipated benefits
3. Selection of subjects is equitable
4. Informed consent will be sought from subjects or LARs
5. Informed consent will be documented
6. There is adequate provision of monitoring
7. There is adequate provision to protect the privacy of subjects

How many days does an IRB have to report a change in registration information due to a change in chairperson or contact? - Correct answer 90 days

How many days does an IRB have to inform the FDA that it is reviewing different types of FDA products? - Correct answer 30 days

How often must an IRB renew it's registration? - Correct answer 3 years

What are the 8 basic elements of informed consent per FDA guidelines? - Correct answer 1. Statement that the study involves research, purpose and expected duration, description of experimental procedures
2. Description of reasonably foreseeable risks
3. Benefits
4. Disclosure of alternative procedures or courses of treatment
5. Confidentiality measures
6. Compensation and treatments available if injury occurs

We do gain our high appraisal by our CCRP quiz torrent and there is no question that our CCRP test prep will be your perfect choice. It is our explicit aim to help you pass it. Our latest CCRP exam torrent are perfect paragon in this industry full of elucidating content for exam candidates of various degree to use. Our results of latest CCRP Exam Torrent are startlingly amazing, which is more than 98 percent of exam candidates achieved their goal successfully.

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.

>> Sample CCRP Questions Answers <<

Real CCRP Dumps | Reliable CCRP Test Sample

Our CCRP study materials have a high quality which is mainly reflected in the pass rate. Our product can promise a higher pass rate than other study materials. 99% people who have used our CCRP study materials passed their exam and got their certificate successfully, it is no doubt that it means our CCRP study materials have a 99% pass rate. So our product will be a very good choice for you. If you are anxious about whether you can pass your exam and get the certificate, we think you need to buy our CCRP Study Materials as your study tool, our product will lend you a good helping hand. If you are willing to take our CCRP study materials into more consideration, it must be very easy for you to pass your exam in a short time.

SOCRA Certified Clinical Research Professional (CCRP) Sample Questions (Q58-Q63):

NEW QUESTION # 58
In accordance with the ICH GCP Guideline, which of the following can an Independent Data Monitoring Committee provide?

- A. Suggestions for a new trial design
- B. An initial review and approval of a trial
- C. The selection of qualified investigators
- 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 # 59
During an IND study closeout, a monitor discovered remaining investigational product. Which procedures must be followed for disposition?

- A. Dispensing pharmacy's procedures
- B. IRB/IEC's procedures
- C. Regulatory authority's procedures
- D. Sponsor's procedures

Answer: D

Explanation:
* ICH E6(R2) 5.13.3:The sponsor is responsible for the supply, storage, and final disposition of investigational product.
* 21 CFR 312.59:Sponsors must assure return or proper disposition of unused supplies.

* Sites must followsponsor's written proceduresfor reconciliation, return, or destruction, not IRB or pharmacy processes.
References:ICH E6(R2) §5.13.3; 21 CFR 312.59.

NEW QUESTION # 60
Which of the following is one of the responsibilities of an investigator?

- A. Participating in the IRB/IEC voting process for approval of their protocol
- B. Selecting qualified monitors on the basis of training, experience, and expertise
- C. Maintaining accurate and current case histories of study subjects
- D. Updating the investigator brochure with new safety information

Answer: C

Explanation:
Investigators are required to maintain accurate subject records, often referred to ascase histories.
* 21 CFR 312.62(b):"An investigator shall prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation."
* ICH E6(R2) 4.9.0:Reinforces that investigators are responsible for recording, handling, and storing clinical trial data.
Incorrect options:
* B: Investigators may present protocols but cannot vote on IRB approval.
* C: Sponsor responsibility (ICH E6 §5.18).
* D: Sponsors are responsible for IB updates (ICH E6 §7.3.1).
Correct answer:A.
References:
21 CFR 312.62(b).
ICH E6(R2), §4.9.0.

NEW QUESTION # 61
After completion of a Phase III trial, which document should IRB/IEC retain?

- A. Sponsor/investigator contracts
- B. Occupations and affiliations of IRB members
- C. Investigational product labels
- D. Subject enrollment logs

Answer: B

Explanation:
* 21 CFR 56.115(a)(5):IRBs must retain records of IRB membership (names, qualifications, affiliations, occupations).
* Other documents (contracts, enrollment logs, product labels) are site or sponsor responsibilities, not IRB's.
References:21 CFR 56.115(a)(5).

NEW QUESTION # 62
Which of the following statements about the investigator's brochure is correct?

- A. It includes financial disclosure information from investigators
- B. It consists of the instructions for the investigator to conduct the study
- C. It contains a summary of the pharmacological and toxicological effects of the drug in animals, and to the extent known, in humans
- D. It provides documents that permit the evaluation of the conduct of the study and the quality of the data

Answer: C

Explanation:
TheInvestigator's Brochure (IB)is a critical regulatory document designed to provide investigators with comprehensive knowledge about an investigational product.
* ICH E6(R2) 7.1:Defines the IB as "a compilation of the clinical and nonclinical data on the investigational product(s) that are relevant to the study of the product(s) in human subjects."

* ICH E6(R2) 7.2.2:Specifies the IB should contain asummary of pharmacological, toxicological, pharmacokinetic, and metabolic studies in animals, as well as results from previous human experience.
* The purpose is to allow investigators to makerisk-benefit assessments, support protocol design, and ensure subject safety.
Incorrect options:
* A (instructions to conduct study) describes theprotocol, not the IB.
* C (financial disclosures) are required under21 CFR 54, not part of the IB.
* D refers totrial master file/essential documents, not the IB.
Therefore, the IB's defining function is to provide ascientific summary of preclinical and clinical data supporting safe human use.
References:
ICH E6(R2), §7.1, §7.2.2.

NEW QUESTION # 63
.....