
SOCRA Exam Study Guide 100% Verified Graded A 2024

When isn't an IND application needed? - IND Application is not needed if investigation does not support change in labeling.

What information must the general IND include?

(21 CFR Part 312.23) - -FDA Form 1571

-FDA Form 1571 cover sheet

-Table of contents

-Investigative Plan

-Investigator's brochure

-Protocol

-Chemistry/Manufacturing information

-Pharmacology/Toxicology

-Previous human research/literature information

-Additional information (drug dependence and abuse potential)

How many days after FDA receives IND submission does the IND go into effect? 21

CFR 312.40 - (Administrative Actions) An IND goes into effect 30 days after the FDA receives the submission unless the FDA notifies the Sponsor of a clinical hold.

When must an IND amendment be submitted and which section outlines this? - (21 CFR Part 312.31)

-If there are changes to the protocol that affects safety of subjects, scientific quality of study, or scope of investigation

-If a new Investigator is added to the study

-Information amendments must be submitted for chemistry/microbiology, pharm/toxicology, or clinical

Other submissions:

--IND safety reports

--Response to clinical hold

--Response to FDA request for information

--IRB Annual report

What are the requirements for expanded access? 21 CFR Part 312.300 (Subpart 1) - -

Population must have serious or life-threatening disease or condition

-No comparable/significant alternate therapy/treatment

-Patient cannot obtain drug under another IND or protocol

-Potential benefit outweighs risks of treatment

-Expanded access won't interfere with completion of studies that could support marketing approval

-Must apply to treatment protocols and should be for individual use (1 person)

Study Guide For Socra Exam

Pramod Lad



Study Guide For Socra Exam:

Ccrp Exam Study Guide Pramod Lad, 2019-03-24 This is a companion volume to the CCRP EXAM WORKBOOK. The sequence of chapters is the same in both books to facilitate parallel review. The study guide provides the didactic material while the exam workbook provides test questions pertaining to it. For maximum effectiveness in exam preparation, the two volumes should be studied together. Clinical research management, including the management of clinical trials, is a complex activity involving several different individuals with varying educational and professional backgrounds. Research investigators, clinical research coordinators, research nurses, monitors, IRB staff, regulatory personnel, to name a few, all play an important role in clinical trial and clinical research management. The Society of Clinical Research Associates (SOCRA) provides an important forum for the education and training of clinical research professionals. A significant component of this training is the certification exam, which results in the CCRP Certified Clinical Research Professional designation. This designation is particularly important to clinical research coordinators and research nurses who provide the main site-associated support for clinical trial and clinical research management. The certification serves as an important milestone in career development and can assist clinical research coordinators in careers in both academic and teaching hospitals, CROs, as well as within the pharmaceutical industry. The examination evaluates knowledge, understanding, and application of the conduct of clinical research and clinical trials involving humans. It tests the familiarity with the International Conference on Harmonisation Guideline for Good Clinical Practice (ICH GCP), ICH Clinical Safety Data Management Definitions and Standards for Expedited Reporting (E2A), the United States Code of Federal Regulations (CFR), and the ethical principles that guide clinical research consistent with the principles of the Nuremberg Code, the Belmont Report, and the Declaration of Helsinki. This study guide provides one tool for the preparation and study for the CCRP examination. The book addresses the key issues in ICH GCP, federal regulations outlined in statutes including Title 45, part 46, Protection of Human Subjects; Title 21, part 50, Protection of Human Subjects; Title 21, part 56, Institutional Review Boards; Title 21, part 54, Financial Disclosures by Clinical Investigators. Also addressed are key FDA statutes involved in the regulation of clinical trials: Title 21, part 312, Investigational New Drug Application; Title 21, part 812, Investigational Device Exemptions; and Title 21, part 11, Electronic Records and Electronic Signatures. The CCRP exam covers material based not only on these regulations but also on guidances issued by OHRP and the FDA. The study guide is organized in distinct chapters, each of which covers one aspect of the regulations or guidances. The chapters are deliberately designed to instruct on core materials. The study guide is therefore designed not only to prepare for the CCRP examination but also to educate clinical research professionals, particularly clinical research coordinators and research nurses, on matters which arise frequently in clinical research management and administration.

Ccrp Exam Workbook Pramod Lad, 2018-10-09 Clinical research management, including the management of clinical trials, is a complex activity involving several different individuals with varying educational and professional backgrounds.

Research investigators clinical research coordinators research nurses monitors IRB staff regulatory personnel to name a few all play an important role in clinical trial and clinical research management The Society of Clinical Research Associates SOCRA provides an important forum for the education and training of clinical research professionals A significant component of this training is the certification exam which results in the CCRP Certified Clinical Research Professional designation This designation is particularly important to clinical research coordinators and research nurses who provide the main site associated support for clinical trial and clinical research management The certification serves as an important milestone in career development and can assist clinical research coordinators in careers in both academic and teaching hospitals CROS as well as within the pharmaceutical industry The examination evaluates knowledge understanding and application of the conduct of clinical research and clinical trials involving humans It tests the familiarity with the International Conference on Harmonisation Guideline for Good Clinical Practice E6 ICH GCP ICH Clinical Safety Data Management Definitions and Standards for Expedited Reporting E2A the United States Code of Federal Regulations CFR and the ethical principles that guide clinical research consistent with the principles of the Nuremberg Code the Belmont Report and the Declaration of Helsinki This workbook provides one tool for the preparation and study for the CCRP examination The book addresses the key issues in in ICH GCP federal regulations outlined in statutes including Title 45 part 46 Protection of Human Subjects Title 21 part 50 Protection of Human Subjects Title 21 part 56 Institutional review Boards Title 21 part 54 Financial Disclosures by Clinical Investigators Also addressed are key FDA statutes involved in the regulation of clinical trials Title 21 part 312 Investigational New Drug Application Title 21 part 812 Investigational Device Exemptions and Title 21 part 11 Electronic Records and Electronic Signatures The CCRP exam covers material based not only on these regulations but also on guidances issued by OHRP and the FDA The workbook is organized in distinct chapters each of which covers one aspect of the regulations or guidances The multiple choice questions are deliberately designed to instruct on core materials rather than offering linguistically ingenious choices The workbook is therefore designed not only to prepare for the CCRP examination but also to educate clinical research professionals particularly clinical research coordinators and research nurses on matters which arise frequently in clinical research management and administration

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Table of Contents Study Guide For Socra Exam

1. Understanding the eBook Study Guide For Socra Exam
 - The Rise of Digital Reading Study Guide For Socra Exam
 - Advantages of eBooks Over Traditional Books
2. Identifying Study Guide For Socra Exam
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Study Guide For Socra Exam
 - User-Friendly Interface
4. Exploring eBook Recommendations from Study Guide For Socra Exam
 - Personalized Recommendations
 - Study Guide For Socra Exam User Reviews and Ratings
 - Study Guide For Socra Exam and Bestseller Lists
5. Accessing Study Guide For Socra Exam Free and Paid eBooks
 - Study Guide For Socra Exam Public Domain eBooks
 - Study Guide For Socra Exam eBook Subscription Services
 - Study Guide For Socra Exam Budget-Friendly Options
6. Navigating Study Guide For Socra Exam eBook Formats
 - ePub, PDF, MOBI, and More
 - Study Guide For Socra Exam Compatibility with Devices
 - Study Guide For Socra Exam Enhanced eBook Features
7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Study Guide For Socra Exam
 - Highlighting and Note-Taking Study Guide For Socra Exam
 - Interactive Elements Study Guide For Socra Exam
8. Staying Engaged with Study Guide For Socra Exam

- Joining Online Reading Communities
- Participating in Virtual Book Clubs
- Following Authors and Publishers Study Guide For Socra Exam
- 9. Balancing eBooks and Physical Books Study Guide For Socra Exam
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Study Guide For Socra Exam
- 10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
- 11. Cultivating a Reading Routine Study Guide For Socra Exam
 - Setting Reading Goals Study Guide For Socra Exam
 - Carving Out Dedicated Reading Time
- 12. Sourcing Reliable Information of Study Guide For Socra Exam
 - Fact-Checking eBook Content of Study Guide For Socra Exam
 - Distinguishing Credible Sources
- 13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development
 - Exploring Educational eBooks
- 14. Embracing eBook Trends
 - Integration of Multimedia Elements
 - Interactive and Gamified eBooks

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