

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 Socra

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Study Guide Socra:

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 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 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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the spirit and its varied meanings are examined philosophically from a historical and a conceptual perspective **Manual for the Study of Contemporary Civilization** Columbia University,1942 **The CRC's Guide to Coordinating Clinical Research** Karen E. Woodin,2004 This guidebook is filled with valuable information on the role and responsibilities of a clinical research coordinator CRC and explains the research process from the site and CRC perspective Topics covered include identifying the regulations governing clinical research describing the drug development process discussing good clinical practices and how to apply them in clinical trials and organizing a clinical practice **A Clinical Trials Manual From The Duke Clinical Research Institute** Margaret Liu,Kate Davis,2011-08-24 The publication of the second edition of this manual comes at an important juncture in the history of clinical research As advances in information technology make it possible to link individuals and groups in diverse locations in jointly seeking the answers to pressing global health problems it is critically important to remain vigilant about moral and ethical safeguards for every patient enrolled in a trial Those who study this manual will be well aware of how to ensure patient safety along with fiscal responsibility trial efficiency and research integrity Robert Harrington Professor of Medicine Director Duke Clinical Research Institute Durham North Carolina USA The Duke Clinical Research Institute DCRI is one of the world s leading academic clinical research organizations its mission is to develop and share knowledge that improves the care of patients around the world through innovative clinical research This concise handbook provides a practical nuts and bolts approach to the process of conducting clinical trials identifying methods and techniques that can be replicated at other institutions and medical practices Designed for investigators research coordinators CRO personnel students and others who have a desire to learn about clinical trials this manual begins with an overview of the historical framework of clinical research and leads the reader through a discussion of safety concerns and resulting regulations Topics include Good Clinical Practice informed consent management of subject safety and data as well as monitoring and reporting adverse events Updated to reflect recent regulatory and clinical developments the manual reviews the conduct of clinical trials research in an increasingly global context This new edition has been further expanded to include In depth information on conducting clinical trials of medical devices and biologics The role and responsibilities of Institutional Review Boards and Recent developments regarding subject privacy concerns and regulations Ethical documents such as the Belmont Report and the Declaration of Helsinki are reviewed in relation to all aspects of clinical research with a discussion of how researchers should apply the principles outlined in these important documents This graphically appealing and eminently readable manual also provides sample forms and worksheets to facilitate data management and regulatory record retention these can be modified and adapted for use at investigative sites

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