
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

G. J. Van Dijk



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

Revise AS & A2 Physics Study Guide Graham Booth, 2008 **The Prentice Hall Good Reading Guide** Kenneth McLeish, 1988 Αἶνοι, Λόγοι, Μῦθοι Gert-Jan van Dijk, 2018-07-17 The first study to focus on the numerous ancient Greek

fables occurring outside and predating the extant fable collections Divided into three parts its core is an intertextual analysis of the functions of fables and their allusions Here the author covers many different authors and a variety of genres in Archaic Classical and Hellenistic Greek Literature ranging from lyric to historiography from Aristotle to Hesiod and from Agamemnon to Zopyrus This analysis is based on a study of both modern and ancient fable theory the latter having hitherto never been studied in toto and incorporating the Graeco Roman terminology of the genre The book s third part is a collection of all texts and contexts studied which greatly facilitates cross referencing

Spirit in Philosophy Catarina Belo,2019-04-30 Catarina Belo explores the question of spirit in the history of philosophy and in various philosophical disciplines highlighting its meaning and significance for Thomas Aquinas George Berkeley and Georg Wilhelm Friedrich Hegel among other major figures Belo argues that some of the traditional arguments concerning God reason and our knowledge of the world are shared by these philosophers culminating but not ending in Hegel In addition she defends a kind of idealism that is not incompatible with realism The book assumes the form a lively dialogue between a student and a teacher following the literary tradition in philosophy that begins with Plato The question of the spirit and its varied meanings are examined philosophically from a historical and a conceptual perspective

The Bible Study Manual Harold Bruce Hunting,1910 [Ainoi, Logoi, Mythoi](#) G. J. Van Dijk,1997 The first intertextual study of all allusions to fables occurring in Archaic Classical and Hellenistic Greek literature examining both modern and ancient fable theory as well as Greaco Roman terminology of the genre

[The Lunatic Guide to the David Letterman Show](#) Bradford Keeney,1994

Oxford Studies in Ancient Philosophy, Volume 42 Brad Inwood,2012-07-19 Oxford Studies in Ancient Philosophy is a volume of original articles on all aspects of ancient philosophy The articles may be of substantial length and include critical notices of major books OSAP is now published twice yearly in both hardback and paperback The serial Oxford Studies in Ancient Philosophy OSAP is fairly regarded as the leading venue for publication in ancient philosophy It is where one looks to find the state of the art That the serial which presents itself more as an anthology than as a journal has traditionally allowed space for lengthier studies has tended only to add to its prestige it is as if OSAP thus declares that since it allows as much space as the merits of the subject require it can be more entirely devoted to the best and most serious scholarship Michael Pakaluk Bryn Mawr Classical Review

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