

SOCRA Practice Test Exam With Correct Questions And Answers 2024

Which of the following is a disclosure of financial interests form? - CORRECT ANSWERS-FDA Form 3455

Which of the following is a certification of financial interest form? - CORRECT ANSWERS-FDA Form 3454

If the investigator did have financial arrangement with the sponsor, he/she would submit the following form: - CORRECT ANSWERS-FDA Form 3455

This form is submitted by sponsor to the FDA prior to the beginning of the drug trial - CORRECT ANSWERS-Investigational New Drug Application (1571)

In the top right corner, form have OMB number. What does it stand for? - CORRECT ANSWERS-Office of Management and Budget

The form, which is submitted to the FDA to report an Adverse Event is - CORRECT ANSWERS-3500

Medical device adverse events/problems are reported via a form: - CORRECT ANSWERS-3500A

What is FDA form 1571? - CORRECT ANSWERS-Cover-sheet for Investigational New Drug Applications

21 CFR 312 deals with - CORRECT ANSWERS-Investigational New Drug Application

Investigational new drug means - CORRECT ANSWERS-A new drug or biological drug that is used in a clinical investigation

The immediate package of an investigational new drug intended for human use shall bear a label with the statement - CORRECT ANSWERS-"Caution: New Drug—Limited by Federal (or United States) law to investigational use."

Which of the following is not listed on FDA form 1571: - CORRECT ANSWERS-Approved informed consent document

"Any adverse drug experience that places the patient or subject, in the view of the investigator, at immediate risk of death from the reaction as it occurred" is... - CORRECT ANSWERS-Life threatening adverse drug experience

Socra Practice Test For New Exam

Mike Jess

Socra Practice Test For New 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 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 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

Principles and Practice of Pharmaceutical Medicine

Lionel D. Edwards,Anthony W. Fox,Peter D. Stonier,2011-07-12 The new edition of Principles and Practice of Pharmaceutical Medicine is a comprehensive reference guide to all aspects of pharmaceutical medicine New content includes chapters and coverage on regulatory updates increasing international harmonization transitional and probabilistic approaches to drug development the growing sophistication and regulatory importance of pharmacovigilance personalized medicine and growth in biotechnology as a source of new experimental drugs

Research for the Radiation Therapist Caitlin Gillan,Lisa DiProspero,Nicole Harnett,Lori Holden,2014-02-07 This book addresses a wide range of topics from the principles of

evidence based practice to the process and dissemination of research to unique considerations such as clinical trials

patenting and health services research The case for evidence based practice and a collaborative research culture is made first followed by a series of chapters walking the reader through the research process by way of the scientific method One of the more unique aspects of the scope of this book is the inclusion of chapters relating to the dissemination of knowledge manuscript publication and how to build an academic research program Each chapter focuses on introducing the reader to foundational principles methodology and terminology and highlight case studies of radiation therapist research or experience that is relevant to provide contextual examples and inspiration to the reader

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