Practice Questions for SOCRA exam | 105 QUESTIONS | WITH COMPLETE SOLUTIONS

Which of the following is a disclosure of financial interests form? Correct Answer:

Which of the following is a certification of financial interest form? Correct Answer:

If the investigator did have financial arrangement with the sponsor, he/she would submit the following form: Correct Answer:

This form is submitted by sponsor to the FDA prior to the beginning of the drug trial Correct Answer: Investigational New Drug Application

In the top right corner, form have OMB number. What does it stand for? Correct Answer:

The form, which is submitted to the FDA to report an Adverse Event is Correct Answer:

Medical device adverse events/problems are reported via a form: Correct Answer:

What is FDA form 1571? Correct Answer:

21 CFR 312 deals with Correct Answer:

Investigational new drug means Correct Answer: 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 wit the statement Correct Answer:

Which of the following is not listed on FDA form 1571: Correct Answer: a. name, address, phone number of the sponsor

b, a commitment not to start the clinical investifation until the InD is in effect

c. identification of the phase of the trail

d. 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 Answer: a. serious adverse drug experience

b. life threatening adverse drug experience

c, none of the above

What are the three main basic ethical principles of the Belmont Report? Correct Answer: 1. Respect for Persons

2. Beneficence

3. Justice

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Tim Dornan, Karen V. Mann, Albert J J A Scherpbier, John A. Spencer

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connections among the various strands of Plato's thought The book includes an index of passages to guide students through parts of the Republic that they find challenging Implementing Interactive Learning Strategies in Higher Education Railean, Elena Aurel, 2024-08-01 Higher education faces the ongoing challenge of engaging students in successful lifelong learning despite rapidly evolving environments Traditional teaching methods need to be revised to prepare students for the complexities of modern society as they currently leave a gap between theory and practice To address this dilemma Implementing Interactive Learning Strategies in Higher Education offers a comprehensive framework and the latest empirical research to help educators address students diverse learning needs The book focuses on active and interactive learning strategies cognitive and metacognitive approaches and social emotional learning techniques It provides practical insights for educators across disciplines including adaptive learning strategies and innovative digital engagement methods

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 Tile 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

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The Broadview Anthology of Social and Political Thought - Volume 1: From Plato to Nietzsche Andrew Bailey, Samantha Brennan, Will Kymlicka, Jacob T. Levy, Alex Sager, Clark Wolf, 2008-03-06 This comprehensive volume contains much of the important work in political and social philosophy from ancient times until the end of the nineteenth century The anthology offers both depth and breadth in its selection of material by central figures while also representing other currents of political thought Thucydides Seneca and Cicero are included along with Plato and Aristotle Al Farabi Marsilius of Padua and de Pizan take their place alongside Augustine and Aquinas Astell and Constant are presented in the company of Locke Rousseau and Wollstonecraft The editors have made every effort to include translations that are both readable and reliable Every selection has been painstakingly annotated and each figure is given a substantial introduction highlighting his or her major contribution within the tradition In order to ensure the highest standards of accuracy and accessibility the editors have consulted dozens of leading academics during the course of the anthology s development a number of whom have contributed introductory material as well as advice The result is an anthology with unparalleled pedagogical benefits and one that truly breaks new ground English Journal ,1992 **Socrates and the Immoralists** Curtis N. Johnson, 2005-01-01 Socrates and the Immoralists assembles an in depth exploration of Socrates argument for the just life focusing specifically on the dialogues with the immoralists Polus Callicles and Thrasymachus and illuminates the complexities of Socrates thought showing the interplay of the seemingly contradictory parts of Socrates ambition ultimately vindicating the overall coherence of his views Middle Range Theory for Nursing Mary Jane Smith, Patricia R. Liehr, Roger D. Carpenter, 2023-01-25 Three time recipient of the AJN Book of the Year Award The completely revised fifth edition of this authoritative text encompasses the most current middle range theories for graduate nursing students and researchers User friendly and consistently organized it helps readers to understand the connection of research to larger conceptual models in nursing The fifth edition presents three new theories a revised chapter on concept building two published examples demonstrating the concept building process and a new section on the application of middle range theory that addresses its use for practice and education Additional new features include the fresh perspectives of a third editor a two color design to enhance readability and discussion questions concluding each chapter The text describes sixteen middle

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Philosophy and Philosophers John Shand,2014-12-18 This revised and updated edition of a standard work provides a clear and authoritative survey of the Western tradition in metaphysics and epistemology from the Presocratics to the present day Aimed at the beginning student it presents the ideas of the major philosophers and their schools of thought in a readable and engaging way highlighting the central points in each contributor s doctrines and offering a lucid discussion of the next level details that both fills out the general themes and encourages the reader to pursue the arguments still further through a detailed guide to further reading Whether John Shand is discussing the slow separation of philosophy and theology in Augustine Aquinas and Ockham the rise of rationalism British empiricism German idealism or the new approaches opened up by Russell Sartre and Wittgenstein he combines succinct but insightful exposition with crisp critical comment This new

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