
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 with 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 investigation until the IND is in effect

c. identification of the phase of the trial

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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Christian Drosten



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Medical Education: Theory and Practice E-Book Tim Dornan, Karen V. Mann, Albert J J A Scherpbier, John A. Spencer, 2011-12-02 Medical Education Theory and Practice is a new text linking the theory and the practice for graduate students and educators who want to go beyond the basics The scholarship of medical education is above all a practice but one that has a strong theoretical foundation Neither theory nor practice stand still and both are grounded in research The novelty of this book lies in its interweaving of practice theory innovation and research The book starts with a theorised contemporary overview of the field Next it explores the theoretical foundations of medical education in depth The remainder of the book reviews a whole a range of educational contexts processes and outcomes This work has been edited by a distinguished international team of medical educationalists and written by equally accomplished authors from across the globe representing a spectrum of disciplines This will be an invaluable text for all Masters Students in health professions education as well as PhD students and education researchers wanting a background to the discipline Educators and medical students will also find it a very useful resource Written by key figures in medical educational research combined with a strong editorial influence from the international editorial team The text has a strong evidence based approach that is fully cognisant of research methodology issues The book provides a scholarly explanation on the topic rather than aiming to say the last word Written throughout in a clear and comprehensible style The content is extensively referenced with additional suggestions for further reading

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

Socratic Seminars in the Block Wanda H. Ball, Pam Brewer, 2000 Shows how teachers can plan and implement Socratic Seminars a strategy that is particularly appropriate for teaching in a block schedule and which leads to active learning

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 *Educational Times* ,1916

Student Lawyer ,1985 **Plato's Socrates on Socrates** Anne-Marie Schultz,2020-03-19 In Plato s Socrates on Socrates Socratic Self Disclosure and the Public Practice of Philosophy Anne Marie Schultz analyzes the philosophical and political implications of Plato s presentation of Socrates self disclosive speech in four dialogues Theaetetus Symposium Apology and Phaedo Schultz argues that these moments of Socratic self disclosure show that Plato s presentation of Socrates the narrator is much more pervasive than the secondary literature typically acknowledges Despite the pervasive appearance of a Socrates who describes his own experience throughout the dialogues Socratic autobiographical self disclosure has received surprisingly little scholarly attention Plato s use of narrative particularly his trope of Socrates the narrator is often subsumed into discussions of the dramatic nature of the dialogues more generally rather than studied in its own right Schultz shows how these carefully crafted narrative remarks add to the richness and profundity of the Platonic texts on multiple levels To illustrate how these embedded Socratic narratives contribute to the portrait of Socrates as a public philosopher in Plato s dialogues the author also examines Socratic self disclosive practices in the works of bell hooks Kathy Khang and Ta Neishi Coates and even practices the art of Socratic self disclosure herself *The New York Times Biographical Service* ,1988 A compilation of current biographical information of general interest **The Spectator** ,1981 A weekly review of politics literature theology and art

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