Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance

Fay A. Rozovsky, Rodney K. Adams
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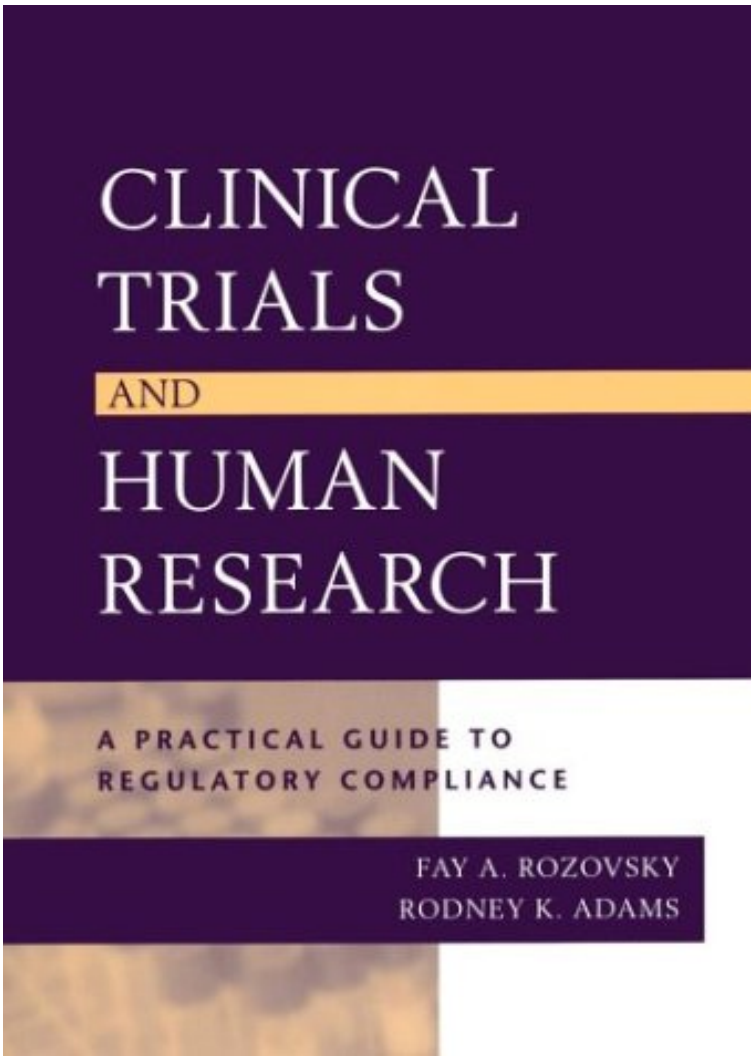

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Fay A. Rozovsky, Rodney K. Adams : Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance before purchasing it in order to gage whether or not it would be worth my time, and all praised Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance:

0 of 0 people found the following review helpful. Clinical Trials...Regulatory ComplianceBy Psych MajorI like the way this book makes IRB's, HIPAA, and research policies easy to understand. It also offers great references of resources within the government agencies that enforce these Rules.

This easy-to-read reference book provides a practical approach for dealing with the legal and regulatory compliance issues involved in human research. Covering a broad range of topics, such as consent, confidentiality, subject recruitment and selection, the role of the investigator and Institutional Review Board, it offers timely and useful strategies for achieving regulatory compliance while reducing liability. In addition, insurance, quality management, accreditation, and risk management are topics examined in the book. The practical insights found in this volume are not found in other books on the subject. Clinical Trials and Human Research is a practical tool to help anyone involved in clinical research.

"Ideal for anyone who wants a comprehensive understanding of clinical research" (Journal of Clinical Research Best Practices)From the Back CoverThis easy-to-read reference book provides a practical approach for dealing with the legal and regulatory compliance issues involved in human research. Covering a broad range of topics, such as consent, confidentiality, subject recruitment and selection, the role of the investigator and Institutional Board, it offers timely and useful strategies for achieving regulatory compliance while reducing liability. In addition, insurance, quality management, accreditation, and risk management are topics examined in the book. The practical insights found in this volume are not found in other books on the subject. Clinical Trials and Human Research is a practical tool to help anyone involved in clinical research. Praise for Clinical Trials and Human Research "I would recommend the book for anyone new to the Institutional Board process, regardless of their clinical or administrative background or responsibilities. It is a valuable resource to orient risk managers, clinicians, and administrators to the clinical trial process and pitfalls." Deborah Boyd, M.S., R.H.I.A., C.P.H.R.M., senior risk management consultant, Zurich North America, Atlanta, Georgia "As more and more research programs get into trouble, there's been a mad scramble to get on top of the problems. The logical starting point is regulatory compliance. Researchers and research administrators must understand the regulations if they hope to achieve high ethical standards in the performance of human subjects research. This thoughtful and well-organized book should be read by anyone who is interested in human subjects research, such as bioethicists, researchers, IRB and DSMB members, and study sponsors." Evan DeRenzo, Ph.D., Center for Ethics at Washington Hospital Center, Washington, D.C., The Johns Hopkins University, Baltimore, MarylandAbout the AuthorFay A. Rozovsky,Fay A. Rozovsky, J.D., M.P.H. is an affiliate associate professor in the Department of Legal Medicine at Virginia Commonwealth University's School of Medicine. Ms. Rozovsky has served as the administrator of an Institutional Board and is a member of human research committees in the United States and Canada. Rodney K. Adams, J.D., L.L.M., is an attorney in Richmond, Virginia, where he specializes in defending healthcare providers and patient care issues. Mr. Adams is cochairman of the American Bar Association subcommittee on medical ethics. He also is adjunct assistant professor at University of Richmond, T. C. Williams College of Law, Richmond, Virginia.