“Becoming a Successful Clinical Research Investigator”

David Ginsberg, with contributions by Norman M. Goldfarb, Barry Miskin, Ann Neuer and Kane Woodin, 2005, 379 pages, Thomson CenterWatch, $79.00

Review by David Vulcano


Sara Gambrill, editor, deserves our congratulations for bringing this book to print. The industry has changed a lot since 1997, when the first edition of the previous book was published. Among other changes, we are now in an industry under great stress, so it is difficult to provide accurate perspectives and give practical advice without offending someone or scaring off the new investigators that need this book to get up the learning curve.

The book is essential reading for new and potential investigators in the United States, but is useful for anyone who wants to understand how to run an investigative site anywhere in the world. Even seasoned investigators will probably learn something from the book, which provides detailed practical advice on numerous important topics. I encourage sponsors to distribute copies to their new investigators, so they won’t be surprised by the challenges of conducting clinical research... in the middle of the trial. Sponsor and CRO personnel who want to work more effectively with sites should read the book as well.

The book includes 166 pages of text, 36 pages of forms, and 171 pages of regulations. Topics covered include:

- Is Clinical Research for Me?
- Drug Development
- Business Development
- Hiring and Retaining Clinical Research Coordinator(s)
- Basic Infrastructure: Space Planning, SOPs and Financing
- Understanding the Regulations and Good Clinical Practice (GCP)
- Interacting with Institutional Review Boards (IRBs)
- Informed Consent
- Preparing for a Study
- Working with Study Subjects
- Study Closure
- Adverse Events and Safety Monitoring
- Audits

The book is available in the professional bookstore at www.centerwatch.com.

Editor’s note: As a “contributor,” I did not have the opportunity to review the manuscript before it went to press. Contact me at ngoldfarb@firstclinical.com for a list of comments on the text, or for an autographed copy.

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