

## **"Conducting Clinical Research: A Practical Guide for Physicians, Nurses, Study Coordinators, and Investigators, 2<sup>nd</sup> Edition"**

**Judy Stone, 2010, 624 pages, Mountainside MD Press, \$79.95**

**Review by Norman M. Goldfarb**

"Conducting Clinical Research: A Practical Guide for Physicians, Nurses, Study Coordinators, and Investigators, 2<sup>nd</sup> Edition" combines practical tips and tools for conducting research with thoughtful discussions of social and ethical issues. Both elements are essential for anyone conducting clinical research. The writing is clear and practical, for example in these two excerpts:

One bizarre and confusing question that everyone has trouble keeping straight,

especially if they are juggling more than one study, is, "What is Day 1?" There is a surprising and bewildering array of answers to this question. And, while it sounds trivial, all study activities are based on the definition of Day 1. Some companies define Day 1 as the day of the patient's enrollment, up to midnight of that day. For others, it is the first 24-hour period after enrollment, regardless of the calendar day. Yet others call enrollment day "Day 0."

One caveat is to be aware, especially with long-term studies, that the patients may want to please you to the point of not wanting to confess to problems with compliance with the study regimen's medications or by minimizing their discomfort. This recently became an issue with a patient on a three-year rheumatoid arthritis study. Toward the end of that period, she developed progressive symptoms but did not want to drop out of the trial. I had to remind her that her health came first and that it was inappropriate for her to continue on this trial. This desire to please and to not disappoint the doctor is particularly a problem among patients drawn from your own private practice or with whom you have a longstanding relationship. Again, you need to be careful that the patient neither feels coercion to continue nor becomes worried about how dropping from a trial might affect future care.

The book includes 10 chapters:

- Overview
- Scrounging Your First Study
- Reality Testing: Feasibility, Budgets and Contracts
- Regulatory Issues
- Study Start-Up
- Study Activities: Strategies and Tools
- Perspective on the State of the Industry\*
- Ethical Issues in Human Subjects Research
- Society and Politics
- Opportunities and Training in Clinical Research\*

\* New chapter in this edition

This book has been selected for  
[The First Clinical Research Bookshelf](#)  
Essential reading for clinical research professionals

Five of the ten chapters (111 pages) provide very practical, hands-on advice about conducting clinical research. The other chapters provide background and context with discussions of topics such as protocol design and ethical issues. Ninety-four pages of appendices include links to numerous resources. More than 50 forms and worksheets are available at <http://conductingclinicalresearch.com>.

The book is available at <http://conductingclinicalresearch.com/index.html> and in bookstores.

### **Reviewer**

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