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"Can You Handle the Truth?"

"Conducting Clinical Research: A Practical Guide for Physicians, Nurses, Study Coordinators, and Investigators"

Judy Stone, 2006, 427 pages, Mountainside MD Press, \$69.95

Review by Norman M. Goldfarb

"Conducting Clinical Research: A Practical Guide for Physicians, Nurses, Study Coordinators, and Investigators" combines practical tips and tools for conducting research with thoughtful discussions of ethical and social issues. Both are essential for anyone conducting clinical research. The writing is detailed, clear and often amusing. For example:

Protocol exceptions must be well documented. Put a note in the source documents and in the CRF, if possible. This note should include the date and time of the call to the medical monitor (or CRA), what the deviation from the inclusion or exclusion criteria was, and the fact that the exception was authorized by the medical monitor, giving the physician's name. Otherwise, when monitored, your assessments will be plastered the reproachful "protocol violation" and the sponsor will not pay for an otherwise completely evaluable patient.

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

The book includes nine chapters:

- Overview
- Scrounging Your First Study
- Reality Testing: Feasibility, Budgets, and Contracts
- Regulatory Issues
- Study Start-Up
- Study Activities: Strategies and Tools
- Ethical Issues in Human Subjects Research
- Society and Politics
- Opportunities and Training in Clinical Research

Five of the nine 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. Over 200 pages of appendices include numerous forms and templates.

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

Reviewer

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