

"Writing Clinical Research Protocols: Ethical Considerations"

Evan G. Derenzo and Joel Moss, 2006, 300 pages, Elsevier Academic Press, \$43.95

Review by Norman M. Goldfarb

"Writing Clinical Research Protocols: Ethical Considerations" may be the only book written to date about writing (and reviewing) clinical research protocols. Fortunately, it emphasizes the ethical aspects, and it does so within a comprehensive review of the entire protocol. In the process, it also provides a handy primer on clinical research. Given the foibles (to put it kindly) of many study protocols, how could anyone who participates in writing them not read this book?

The authors note that, in most industry-sponsored protocols, the ethics section discusses regulatory compliance rather than ethics. They propose that the current section be renamed "regulatory compliance," so a new section can focus on important ethical questions such as:

This book has been selected for
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Essential reading for clinical research professionals

- Is this a study that needs to be done?
- What aspects of the protocol present concern for subject safety?
- Are there any aspects of the protocol that diverge from accepted standards of medical practice?
- If so, what risks of harm are created by the divergence?
- What is the ethical justification for the divergence and the risks posed?

The book includes 15 chapters:

- Introduction to the Art and Science of Clinical Research
- What You Need to Know About Clinical Research Ethics
- What You Need to Know About the Regulation of Clinical Research
- Designing a Clinical Research Study
- Selecting Subjects for Clinical Studies
- Risks and Benefits in Clinical Research
- Recruiting Subjects
- Informed Consent
- Privacy and Confidentiality
- The "Ethics" Section
- Procedures and Methods
- Statistics, Data Collection and Management, and Record Keeping
- Use of Human Biological Materials
- Special Issues Raised by Evolving Areas of Clinical Research
- Case Histories: Learning from Experience

The book is available in bookstores.

Reviewer

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