

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

Fay A. Rozovsky and Rodney K. Adams, 2003, 639 pages, Jossey-Bass, \$145.00

Review by Norman M. Goldfarb

"Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance" attempts a comprehensive review of the statutory and regulatory rules for clinical research, and succeeds brilliantly, in a mere 639 pages. Unlike other books that primarily cut-and-paste text from government websites, the book summarizes and explains FDA, Common Rule, and ICH requirements in concise, straightforward prose. It weaves in material from a variety of sources to clarify how the rules can be applied. The book is ideal for anyone who wants a comprehensive understanding of clinical research compliance requirements, or needs a handy reference when questions come up, as they inevitably will.

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

The book includes 18 chapters:

- The Evolution of Human Experimentation Regulation
- Current Federal Regulations and Agencies Involved in Human Research
- State Regulation of Human Research
- Selection and Recruitment of Human Subjects
- Informed Consent in Human Trials
- Confidentiality of Clinical Trials Information
- The Investigator
- Research Protocols
- The Institutional Review Board
- Patient Safety in Clinical Trials Research
- Human Research Under the Food, Drug & Cosmetic Act
- Behavior Research
- Multisite and Collaborative Studies
- Medical Malpractice Liability in Human Research
- Quality Improvement, Accreditation, and Risk Management in Clinical Trials
- Corporate Compliance and Human Research
- Ethics in Human Research
- International Research

The book is available at bookstores.

Reviewer

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