

"Principles and Practice of Clinical Research, Second Edition"

John I. Gallin and Frederick P. Ognibene, editors, 2007, 430 pages, Academic Press, \$99.95

Review by Norman M. Goldfarb

"Principles and Practice of Clinical Research, Second Edition" includes 29 essays about important topics in clinical research and related areas. The essays do not cover day-to-day practicalities for clinical research coordinators and clinical research associates. Rather, they provide ethical, regulatory, statistical, scientific and other perspectives that make sense of the day-to-day details.

Almost all of the authors are with the National Institutes of Health, but most of the material is applicable to both government- and industry-funded research.

Some of the topics, e.g.,

"Researching a Bioethical Question," "Clinical Research: A Patient Perspective," and "The Clinical Researcher and the Media," are unavailable in other clinical research books.

Stephen Straus's essay, "Unanticipated Risk in Clinical Research," relates a fascinating story about what happened to the author when he did everything right as an investigator and scientist except stumble across a previously unknown serious adverse reaction in testing a drug for Hepatitis B viral infections.

Ezekiel Emanuel's essay, "Researching a Bioethical Question," explains and gives examples of different types of bioethics research methods: historical, conceptual, cross-cultural, empirical and policy analysis. Cross-cultural empirical research revealed, for example, that 65% of Anglo-Americans believe patients should make decisions about using life-sustaining technologies, but only 41% of Mexican-Americans and 28% of Korean-Americans agreed.

Susan Lowell Butler's essay, "Clinical Research: A Patient Perspective," includes numerous insights and practical tips for recruiting and retaining study subjects. For example, clinical research impacts not only the life of study subjects; it can also disrupt the lives of their caregivers, i.e., family members. Neglecting their needs is a recipe for failure.

The book consists of 29 essays:

- A Historical Perspective on Clinical Research
- Ethical Principles in Clinical Research
- Researching a Bioethical Question
- Integrity in Research: Individual and Institutional Responsibility
- Institutional Review Boards
- Data and Safety Monitoring Boards
- Data Management in Clinical Trials
- Unanticipated Risk in Clinical Research
- The Regulation of Drugs and Biological Products by the Food and Drug Administration
- Legal Issues

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

- Rules to Prevent Conflict of Interest for Clinical Investigators Conducting Human Subjects Research
- National Institutes of Health Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research
- Clinical Research: A Patient Perspective
- The Clinical Researcher and the Media
- An Introduction to Biostatistics: Randomization, Hypothesis Testing, and Sample Size Estimation
- Design and Conduct of Observational Studies and Clinical Trials
- Small Clinical Trials
- Large Clinical Trials and Registries – Clinical Research Institutes
- Using Secondary Data in Statistical Analysis
- An Introduction to Survival Analysis
- Measures of Function and Health-Related Quality of Life
- Overview of Technology Development
- Technology Transfer
- Writing a Protocol
- Evaluating a Protocol Budget
- Data Management in Clinical Research: General Principles and a Guide to Sources
- Getting the Funding You Need to Support Your Research: Navigating the National Institutes of Health Peer Review Process
- Clinical Research from the Industry Perspective
- Human Genome Project, Genomics and Clinical Research

The book is available in bookstores.

Reviewer

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