

"Designing Clinical Research, 3rd Edition"

Stephen B. Hulley, Steven R. Cummings, Warren S. Browner, Deborah G. Grady, and Thomas B. Newman, 2007, 367 pages, Lippincott Williams & Wilkins, \$79.95

Review by Norman M. Goldfarb

"Designing Clinical Research, 3rd Edition" is a practical, common-sense guide for research investigators, as well as other research professionals who want to understand how their work fits into the big picture. The book covers a broad range of human subject research — translational, clinical trial, patient-oriented, epidemiological, behavioral and health services — from fundamental concepts to functional ethics to funding proposals.

Research questions should meet the "FINER" criteria: feasible, interesting, novel, ethical and

relevant. Once the question is asked, the important criterion becomes good design, the main focus of this book. These criteria seem obvious, but apparently not to the authors of thousands of misconceived studies that will be published this year. In the absence of evidence to the contrary, we will assume that none of them has read this book.

The few formulae in the book are confined to the chapter on sample size and power. Statistical analysis and publication are not covered.

The book consists of 19 chapters:

- Getting Started: The Anatomy and Physiology of Clinical Research
- Conceiving a Research Question
- Choosing the Study Subjects: Specification, Sampling and Recruitment
- Planning the Measurements: Precision and Accuracy
- Getting Ready to Estimate Sample Size: Hypotheses and Underlying Principles
- Estimating Sample Size and Power: Applications and Examples
- Designing a Cohort Study
- Designing Cross-Sectional and Case-Control Studies
- Enhancing Causal Inference in Observational Studies
- Designing a Randomized Blinded Trial
- Alternative Trial Designs and Implementation Issues
- Designing Studies of Medical Tests
- Utilizing Existing Databases
- Addressing Ethical Issues
- Designing Questionnaires and Interviews
- Data Management
- Implementing the Study and Quality Control
- Community and International Studies
- Writing and Funding a Research Proposal

The book is available in bookstores.

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

Reviewer

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