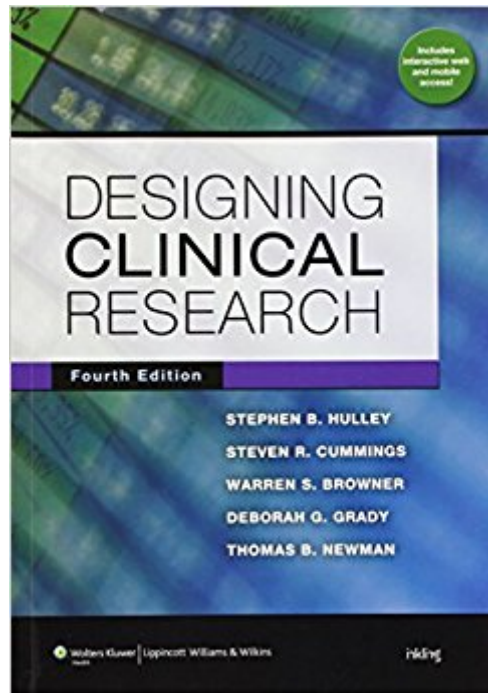




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# Designing Clinical Research



## Synopsis

Publisher's Note: Products purchased from 3rd Party sellers are not guaranteed by the Publisher for quality, authenticity, or access to any online entitlements included with the product. *Designing Clinical Research* has been extensively revised and continues to set the standard as a practical guide for doctors, nurses, pharmacists, and other health professionals involved in all forms of clinical, translational, and public health research. It presents advanced epidemiologic concepts in a reader-friendly way, and suggests common sense approaches to the challenging judgments involved in designing, funding, and implementing. New to this edition: Expanded and updated content in every chapter, with new material on: • non-inferiority trials for comparative effectiveness research • incidence-density case-control studies • confounding and effect modification • diagnostic test studies to inform prediction rules • ethical aspects of whole genome sequencing • automated data management approaches • new NIH grant-writing requirements Color format, and Electronic access, powered by Inkling, as a free companion to the text • viewable through your browser or as a download to tablet or smartphone • the complete text with optimized navigation • note-sharing, highlighting and bookmarking capability • cross-linking of references and content • rapid search options linked to the new glossary

## Book Information

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## Customer Reviews

Clinical Trials have evolved over the past few decades in multiple dimensions. There are legal, regulatory, statistical, procedural, and clinical dimensions which tend to structure them in ways

which were not prevalent to anyone who entered medicine decades earlier. The book by Hulley et al, *Designing Clinical Research*, is a wonderful overview of most of these dimensions. It brings the reader up to date with many of the key factors which have become part of Trials and give an excellent amount of depth so that the book stands on its own. The book is divided into three major sections; (i) Basics including sampling, trial hypotheses testing and statistical analyses as well and general trial types. (ii) Designs which examines the various types of trials from randomized case control, cross-sectional, and other such classic trial methodologies, (iii) Implementation, including the ethical issues and data management. The Basics provides a reasonable overview of the randomization, sizing, and the establishment of the statistical plan for a Trial. The approach is classic with the null hypothesis approach and the metrics necessary for properly sizing a successful Trial. The presentation is in a summary nature and the reader is either expected to be familiar with the development of the mathematics or just to use the Tabular approaches as presented. There are excellent discussions on various approaches such as continuous versus dichotomous and the material is useful even for those well experienced in the area. The Designing sections go over the details associated with various Trial approaches and discuss the implementation, and the advantages and disadvantages. Again, even for someone already familiar with the material the authors provide added insight well worth the reading. Again when discussing such elements as likelihood designs and Receiver Operating Characteristics the material is of a summary nature, adequate for both understanding and application but not of any material depth. Yet that was never the objective of the book. Finally in implementation the authors present an excellent discussion of the Ethical Issues that are frequently found in many Trials. There are other elements here as well but the Ethical discussions have become more prevalent to current day Trials. The challenge that this and other works on Trials will be facing are the Trial involving genome based approaches. For example in MDS and the use of demethylating therapeutics such as azacytidine and others one may ask the ethical question; if this is demethylating and methylation is both the cause while also being a control in other cells, how long should one wait to see long term effects? In cases such as the BRAF inhibitors in melanoma, what import is the extension of life if the costs are so great? Also how aggressively should one approach multiple drug therapies? Finally, as we see more genetically specific drugs on a patient by patient basis, can Trials like those discussed herein still be considered a gold standard and if not what then would take their place. Therapeutics targeted at a specific genome type will be difficult to analyze as we have with large Trials discussed in the book. Overall the book is a superb overview of Trials and is worth a read by finishing Med Students, Resident, and even those experienced in Trials. It is well written, logically laid out, considers almost

all the key questions, and presents information adequate for most.

I haven't read it yet, but a quick skim of a few chapters leads me to believe this book is exactly what I was looking for. I am new to clinical research and this book seems perfect for learning all the basics. I am just slightly disappointed that I spent ~\$65 for a new copy, and it came with a bit of damage and fraying on one edge. I guess I'm being picky, but for the price I would have liked the book to be in mint condition. Feels as if I bought it used (although it was in plastic wrapping).

Great for MDs or PhDs wanting to refresh their knowledge on how to design the strongest research methodology they can. Clearly written book discussing different study designs and their pros and cause when trying to establish a causal association between an exposure and a disease event (or intervention and reduced disease event). This book focuses on clinical research, but is often used in public health courses that deal with general community research as well. The fact that it's used often as a textbook is reflected in its very high price point.

An excellent book. Clearly written, very concise. It guides you step by step in designing clinical research. It covers basic points usually underestimated in other books and some critical points as grant proposals.

I read this book during my clinical research studies. I continue reading it after graduation. I always look forward to the re-introduction of the material. At the same time, I learn something new from the book. I would highly recommend it to clinical research students. It is an excellent required and recommended textbook.

For anyone who is interested in clinical research, this is your gateway. easy to comprehend and follow, simple language. a good start in CI

This is a excellent book, used it as part of a class that I am taking in fellowship. One of the simplest yet most informative book I have come across for clinical research design. I am a

Excellent book! Easy to read, and yet dense of useful information. Very enjoyable learning experience.

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