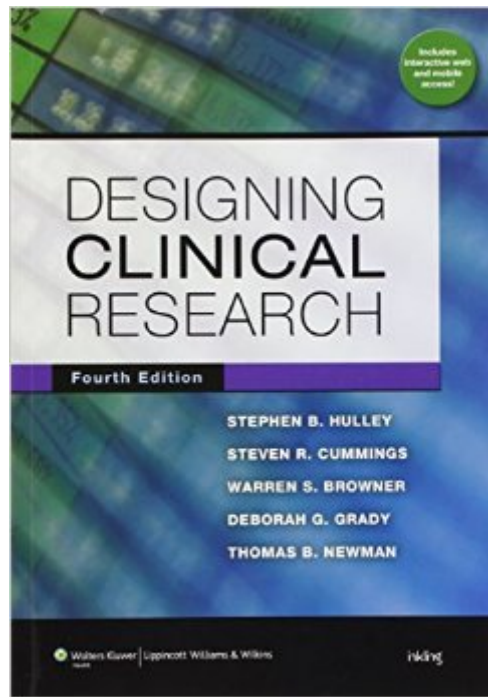


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# Designing Clinical Research



## Synopsis

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

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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.

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