

## "Principles and Practice of Clinical Research, 4<sup>th</sup> edition"

**John I. Gallin, Frederick P. Ognibene, and Laura Lee Johnson, editors, 2018, 806 pages, Academic Press, \$125**

**Review by Norman M. Goldfarb**

"Principles and Practice of Clinical Research, 4<sup>th</sup> edition" is a comprehensive guide to clinical research. Most of the authors are with the National Institutes of Health, but the material is largely applicable to both government- and industry-funded research.

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

A short excerpt illustrates the clear writing and broad scope of the book:

### **Nested Case-Control Studies**

Many prospective cohort studies allow a well-characterized population within which to conduct other studies. A special type of case-control design called a nested case-control study avoids many of the potential pitfalls of classic case-control studies by selecting cases and controls from within a broader population sample established at some time before the onset of disease.

This has become a particularly useful design in large-scale prospective cohort studies with the development of effective collection and storage methods for biologic samples. Serum or plasma (or urine, DNA, etc.) can be collected and stored until a sufficient number of cases has been accumulated to provide adequate study power. At that time, these baseline samples from the newly occurring cases can be thawed and measured, along with a comparison group of matched (or unmatched) controls, allowing a much more efficient approach to examining expensive or difficult-to-measure risk factors. Nested case-control designs are used increasingly in large population studies and avoid many of the biases involved in selection and data collection in cases and controls after the onset of disease.

It has the disadvantage that factors of interest must be in the data already collected and able to be measured in stored samples. Additionally, the condition must be common enough for a sufficient number of cases to develop within a reasonable time and in the cohort sample.

The book includes 42 essays by 72 contributors, including four sections:

- Ethical, Regulatory and Legal Issues
- Study Design and Biostatistics
- Technology Transfer, Data Management, and Sources of Funding Support for Research
- Clinical Research Infrastructure

### **Reviewer**

Norman M. Goldfarb is Managing Director of First Clinical Research LLC, a provider of clinical research best practices information services. Contact him at 1.650.465.0119 or [ngoldfarb@firstclinical.com](mailto:ngoldfarb@firstclinical.com).