

"State-by-State Clinical Trial Requirements Reference Guide, November 2006"

John C. Serio and Dorothy L. Puzio, 194 pages, Barnett Educational Services, \$49.95

Review by Norman M. Goldfarb

The second edition of this indispensable Guide has expanded with updates of various laws and a new section for each state on genetic testing. The Guide is organized by state and covers 12 areas of state law that often impact clinical trials:

- State legal structure regarding clinical trials
- Required notification to state officials
- Protocol requirements
- Legal representative standards
- Age of consent
- Informed consent requirements
- Institutional Review Board requirements
- Special rules for cancer research
- Reimbursement of clinical trial subjects
- Drug supply requirements
- HIV testing
- Genetic Testing

For further research, the Guide also lists state licensing authorities and relevant state statutes and codes for each state.

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

If you are with a sponsor or CRO, you can use the Guide to identify states where subject recruitment may be problematic or costs may be reduced by special incentives or insurance coverage of standard-of-care procedures. The Guide is essential when approving or reviewing subjects in vulnerable groups or requiring consent by a parent or legally authorized representative. In some cases, legal sanctions for site violation of state law may extend to sponsor and CRO personnel. (This means YOU.)

If you are with a site, only a small portion of the book will be directly applicable, but it will be very applicable. You may also find interesting the rules applicable in other states, especially if your state offers financial advantages or fewer restrictions. On the other hand, if your state is relatively restrictive, the information may help support a higher budget proposal.

The Guide is comprehensive, but not complete; it does not claim to be. For example, it does not cover state privacy laws. Nevertheless, it is an excellent reference, and the only one on this topic.

The book is available at <http://www.barnettinternational.com/>

Reviewer

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