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DON'T LEAVE HOME WITHOUT IT:
"STATE-BY-STATE CLINICAL TRIAL REQUIREMENTS REFERENCE GUIDE"
John C. Serio, Jerome B. Tichner, Jr., and Meghan E. Dilley
Barnett Educational Services, 2004, 181 pages, $24.95, ISBN 1-882615-71-9

Review by Norman M. Goldfarb

Just in the nick of time, this indispensable Guide arrives to fill the void created by the demise of Clinlaw. Given its very affordable price, there is no good reason why every clinical research professional involved in regulatory, legal or budget activities should not have a copy on their desk; maybe two copies, in case one is "borrowed."

This book has been selected for
The First Clinical Research Bookshelf
Essential reading for clinical research professionals

The Guide is organized by state and covers 11 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

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 also 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.

Whereas Clinlaw provided pertinent extracts from the laws and regulations without interpretation, the Guide provides straightforward summaries, relying on the actual text only when necessary. The Guide provides citations to relevant state statutes and codes (and state licensing authorities) if further research is required. If Clinlaw ever reappears, its statutory text will nicely complement the Guide's summaries.

The Guide is comprehensive, but not complete; it does not claim to be. For example, left uncovered are preemptive privacy laws such as California's requirement that privacy authorizations include a defined termination date and be printed in 14-point font. The reviewer also hopes that the legal restrictions peculiar to state (and federal) institutions will be added to the next edition. Please send comments to ngoldfarb@firstclinical.com for listing on this website and forwarding to the authors.

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