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"Can You Handle the Truth?"

"Clinical Research Law and Compliance Handbook"

John E. Steiner, Editor, 2006, 488 pages, Jones and Bartlett, \$87.95

Review by Norman M. Goldfarb

If you have ever wondered how compliance officers keep themselves entertained all day, read "Clinical Research Law and Compliance Handbook." If legal, regulatory and ethical compliance is part of your job, the book provides a practical introduction to many complex topics. It will help you keep your institution in the clinical research business and your friends out of jail. On the other hand, your "ignorance" defense will fall by the wayside.

The book includes ten chapters, on the following topics:

- SOPs and training
- Contracts
- Research billing
- Operations and budgets
- Fraud and abuse
- Subject privacy
- Nonregistrational, postmarketing studies
- Institutional review boards (IRBs)
- Conflicts of interest
- Technology for data quality and subject safety

The chapter by Joan Booth and Katherine Hammerhofer includes a sample orientation schedule and competency checklist for clinical research personnel that, by itself, is worth the price of admission. Several chapters cover aspects of billing and reimbursement, an especially tricky area that offers many opportunities to meet law enforcement officers. The Clinical Trial Billing Assessment Workplan and Grants Assessment Audit Program are especially useful appendices.

The book is available at bookstores.

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