

"Institutional Review Board: Management and Function"

Elizabeth A. Bankert and Robert J. Ardur, Editors, 2006, 530 pages, Jones and Bartlett, \$138.95

Review by Norman M. Goldfarb

For IRB management, "Institutional Review Board: Management and Function" is like having the answer key when taking the final exam. Tipping the scales at 3-1/2 pounds, the volume includes 101 essays on topics from the mundane – administrative reporting structures – to the esoteric – alternative medicine research – to the perplexing – risks vs. benefits. An index with over 1,500 entries almost guarantees that at least one of the essays will yield useful background, insight or advice on almost any IRB question likely to arise. For example:

This book has been selected for
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Essential reading for clinical research professionals

- To whom should the IRB chairperson report?
- How should IRB meetings be organized?
- What are the conflict of interest issues for IRB members?
- When are placebo trials acceptable?
- How do you verify that a potential subject understands the informed consent information?
- What are the differences between CFR and ICH? Between FDA and DHHS?
- What are the IRB's responsibilities for humanitarian use devices?

The book is organized in ten sections:

- Background and overview
- Office organization
- IRB committee organization
- Review categories
- Initial protocol review and full-committee meetings
- Informed consent
- Continuing review
- Administrative and regulatory issues
- Study population issues
- Study design and category issues

Unlike some clinical research books that are more than half regulatory reprints, this book is 94% original content. With 96 authors, it's amazing the editors didn't kill someone and find themselves worrying about research on prisoners from behind bars.

The book is available in bookstores. An accompanying study guide (176 pages, \$42.95) is also available.

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