BOOK REVIEW / CRITIQUE DE LIVRE

Clinical Research Coordinator Handbook. By Deborah Norris. 4th ed. Medford, N.J.: Plexus Publishing, 2009. 157 pages (soft cover). ISBN 9780937548707. US$35.00.

The target audience of this publication is novice clinical researchers and (or) graduate students wishing to get a better overall understanding of the research process and continuum. Implementing clinical trials is a detailed and delicate process; this book seeks to provide a nuts-and-bolts guide to establishing protocols, outlining forms, and detailing processes for clinical research.

According to the cover notes, the author has worked in the pharmaceutical industry for many years as a clinical research coordinator, project manager, and director, and is certified to conduct clinical site audits. She has presented on issues of informed consent at conferences and industry training sessions. She is also the author of a second book: *Glossary of Lay Language Synonyms for Common Terms Used in Informed Consent Documents for Clinical Studies: a Handbook for Clinical Researchers* (1996). Deborah Norris is a pseudonym used to avoid the perception of utilizing any current site relationships to obtain financial gain.

The *Clinical Research Coordinators Handbook* (4th edition) is billed as a resource for study coordinators, investigators, and clinical research associates. It includes three sections, each covering a different level of material.

The first section contains brief explanations and checklists applicable to clinical research activity, these include checklists of investigator responsibilities, guidance on creating source documentation, data collection forms, and explanations of the process of obtaining informed consent.

The second section discusses laboratory licensing, FDA inspection, and other federal and state legislation pertinent to research activity. This is, of course, based on United States legislation and is therefore far less valuable to the operation of laboratories and research projects in Canada. However, this section may be of interest to some Canadian-based researchers, as many multi-site trials have data-collection sites around the world and usually originate with large pharmaceutical companies headquartered in the United States.

Finally, the third section contains a detailed set of appendices that provide sample forms such as informed consent letters, adverse events report forms, telephone screening logs, etc. The appendices also include time (standard to military time) conversion tables, imperial to metric measurement conversion, and weight and height conversion tables; these conversion tables can, however, be found many places and seem a bit like filler. The book finishes with a glossary of terms used in clinical trials and a list of standard research abbreviations; again, this material is easily available in other places, such as the Internet.

The book is a fourth edition update; however, I found some interesting anachronisms that indicate the update was superficial. One of the most glaring is the statement about the completion of paper case-report forms, "all entries should be completed legibly using a black ball point pen or a *typewriter*" [my emphasis] (p. 55). How many labs or libraries have a typewriter any more? Can you even get ribbons or tapes?

I was very interested in reviewing this book because I work closely with physicians and research coordinators and I have some responsibility within my hospital for the authorization of research project implementation. New projects for consideration are judged by several criteria to ensure that the projects are scientifically sound, ethically valid, patient friendly, and revenue neutral to our organization. I also interact with research coordinators by monitoring and reporting adverse events, protocol changes, etc. I asked a researcher to read and comment on this book; he felt that the book was quite general, and although the content was accurate, it was geared to an American audience, thus rendering much of the specific content such as legality, FDA audits, HIPPA legislation, etc., irrelevant in the Canadian environment. The researcher did not believe this book would be an appropriate addition to his professional library.

Many of you reading this review will never be involved with clinical research, nor will you be working in an organization that initiates research. However, if you happen to be a librarian who works for a large academic institution or teaching hospital, there may be some utility in having this modestly priced book in your collection.

For those interested in clinical trial development and management, please check out Health Canada's Good Clinical Practices Compliance Program at http://www.hc-sc.gc.ca/contact/dhp-mps/hpfb-dgpsa/insp-gcp-bpc-eng.php. Health Canada runs yearly sessions across the country on Good Clinical Practices. To view the schedule go to: http://www.hc-sc.gc.ca/dhp-mps/consultation/compli-conform/consult2010_gcp-bpc-eng.php.

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