

JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 7, 2011

"Can You Handle the Truth?"

"The CRC's Guide to Coordinating Clinical Research, 2nd Edition"

Karen E. Woodin, 2011, 572 pages, CenterWatch, \$79.00

Review by Norman M. Goldfarb

"The CRC's Guide to Coordinating Clinical Research, 2nd Edition" is a practical handbook for clinical research, with some content tailored for study coordinators (and hands-on investigators). The following extract from the section on drug accountability illustrates the clear writing and level of detail:

The drug must be shipped by the sponsor to a clinical site before that site can begin enrollment in the trial.

Usually the site is alerted before the drug is shipped, so that the correct storage is ready when it arrives. It's also important for the sponsor to alert the site so that the drug is not left unattended and unpacked (e.g., refrigerated product left on a loading dock in hot weather).

When the drug arrives, it will have with it a shipping invoice, which must include the name of the investigator to whom the drug was shipped, the date, quantity and lot numbers of the enclosed drug. Usually the CRC or a pharmacist receives the shipment. The shipping invoice should be checked against the contents of the boxes for accuracy, dated and signed by the receiver, and filed in the study documents. If a pharmacy is maintaining the drug and the pharmacist wants to retain the shipping invoice, it is recommended that the study coordinator make a copy for the study file.

The CRC is usually responsible for managing the investigational product accountability at the site. Careful accounting must be done as the drug is distributed to study subjects. This is normally recorded in the case report forms (CRFs) at each study visit.

There also may be an overall drug distribution form to record the usage for all study subjects throughout the study (sample forms are in Appendix D). Drug accountability sounds pretty simple — you record what is received, what is dispensed to and returned by study subjects, and the amount returned to the sponsor. After all, it's pretty much like balancing your checkbook. But somehow, it doesn't always go smoothly. (I've known people who, when their checkbooks became too inaccurate, just opened new accounts at another bank)

Drug reconciliation should be done throughout the study, rather than left to the end. (Again, think about balancing your checkbook monthly rather than once at the end of the year.) Sometimes, unused drug is returned to the sponsor periodically throughout the study; and it is certainly returned at the end of the study. Drug return is usually done by the CRA, according to company policy. A copy of each drug return inventory form should be kept in the site's study file.

The book includes 15 chapters in 193 pages:

- The Clinical Research Coordinator
- Institutional Review Boards and Data Safety Monitoring Boards
- Informed Consent

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

- Regulations and Good Clinical Practices (GCPs)
- An Overview of Research
- Devices and Biologics
- Standard Operating Procedures (SOPs)
- Preparing for a Study
- Protocols
- Case Report Forms (CRFs and Electronic Data Capture (EDC)
- Investigational Product Accountability
- Working with Study Subjects
- Study Closure
- Adverse Events (AEs) and Safety Monitoring
- Audits

The rest of the book consists of seven appendices that include acronyms, a glossary, resources, sample forms, regulations and other material.

The book is available at <http://www.centerwatch.com> and in bookstores.

Reviewer

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