JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 1, No. 8, August 2005 "Can You Handle the Truth?"

"Good Clinical Practice: A Question & Answer Reference Guide"

Mark P. Mathieu, editor, 2005, 494 pages, Barnett Educational Services, $39.95

Review by Norman M. Goldfarb

"Good Clinical Practice" includes answers to over 300 regulatory questions. But these are not just the obvious questions, and they are not just the simple answers you get by looking up the regulation in a book. Many of the answers consider multiple perspectives and interpret several regulations and guidances to provide an answer that is comprehensive but may not be as cut-and-dried as one would like. After reading this book, you will be skeptical of the regulatory know-it-all who answers a simple question with a simple answer. The good news is that common sense usually prevails – once you understand the factors involved.

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

Questions include:

- Is it considered acceptable for a study coordinator to sign documentation for an investigator?
- If the FDA's view, what is an acceptable monitoring frequency for clinical studies?
- Should expected clinical outcomes of the disease under study, which are efficacy endpoints, be reported as AEs/SAEs?
- What category of study personnel is authorized to administer investigational drugs?
- Are subject enrollment incentives that sponsors offer to clinical trial sites permitted under GCP?
- Can a clinical investigator or site re-schedule an FDA inspection of the site if the investigator will not be available on that date?
- In what ways is the FDA's GCP inspection and compliance program expected to evolve going forward?

A question and answer, chosen literally at random, is in Figure 1.

The book includes 313 pages of Q&A plus 171 pages of U.S. and European regulations. Topics covered include:

- GCP Regulations and Guidelines for Clinical Research
- Investigators/Sites
- Form FDA 1572/Statement of the Investigator
- Clinical Monitoring
- Informed Consent
- Source Data/Documentation
- Clinical Trial Protocols/Protocol Changes/Protocol Violations
- Institutional Review Boards
- Drug/Study Safety and Safety

Figure 1: Would a spouse or immediate family member be classified as an impartial witness under the ICH GCP guidelines?

A spouse or immediate family member might be considered impartial under the ICH GCP guidelines which defines impartial witness as "a person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or subject's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the subject?' Because spouses or immediate family members may face challenges similar to those facing the potential subject (e.g., language, education), these individuals may also be more likely to have problems reading certain words in the informed consent form.

Due to complexities inherent in family relations, it also is possible that immediate family members may have certain conflicts of interest. Therefore, they may not be "impartial" at all, and may not necessarily have the patient's best interest as their primary concern.

Reporting
- Quality Assurance Activities/Study Auditing/FDA Inspections
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- Subject Diaries
- Medical Devices and GCP
- The FDA's Frequently Asked GCP Questions
- Clinical Trials Litigation
- State Laws Affecting Clinical Trials

The book is available at http://www.barnettinternational.com.

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