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"The Form 1572: A Reference Guide for Clinical Researchers, Sponsors, and Monitors"

Marc P. Mathieu, editor, 2008, 134 pages, PAREXEL International Corporation, $45.00

Review by Norman M. Goldfarb

"The Form 1572: A Reference Guide for Clinical Researchers, Sponsors, and Monitors" answers the difficult questions that real life creates from even the simplest regulations. At this very minute, clinical investigators are probably signing erroneous forms because they do not know the correct answers, or even the questions, discussed in this book.

The core of the book is a section-by-section guide to completing the 1572 form. Although the 1572 form, on its surface, seems straightforward, a bit of probing reveals a few myths. For example, the FDA does not require the investigator to personally date his or her signature on the 1572 form, only that the date be accurate. The book also clarifies common points of confusion. For example, if the radiology lab is located within the building where the study is conducted, it does not need to be listed separately in block 3. However, if it is located across the street, it probably should be.

Perhaps the most perplexing section of the 1572 form is block 6, the listing of subinvestigators. For example, does the FDA classify study coordinators as subinvestigators? The answer appears to be that if a study coordinator plays a significant role in collecting and recording data, the answer is "yes." However, if the study coordinator's role is limited to transcribing data, the answer is "no."

A detailed discussion demonstrates that, in general, it is not necessary for sponsors to obtain signed 1572s from non-USA investigators, although there may be reasons to do so in some cases. The book includes quotations from FDA sources that are essential to understanding the basis for this conclusion.

The book consists of four chapters and three appendices:

- Introduction
- The FDA 1572 – Statement of Investigator Form: The Basics
- Completing the Form FDA 1572 – Statement of Investigator: A Section-by-Section Analysis
- Maintaining the 1572 – Statement of Investigator
- Frequently Asked Questions – Statement of Investigator (Form FDA 1572) (Draft Guidance)
- FDA Changes Its Standards for Accepting Data from Foreign, non-IND Clinical Trials
- 1572-Related Excerpts from Good Clinical Practice: A Question & Answer Reference Guide 2008

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

Reviewer

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