

JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 2, No. 1, January 2006

"Can You Handle the Truth?"

"Regulations & Directives Series"

Clinical Research Resources, 2005, 181 to 367 pages, \$9.95 to \$13.95 each

Review by Norman M. Goldfarb

Clinical Research Resources (CRR) publishes a series of 7" X 5-1/2" spiral-bound books for handy reference to U.S. and international regulations, directives and guidances. Books in the series that relate to clinical research include:

- "Selected Regulations and Guidance for Drug Studies" (367 pages)
- "Selected Regulations and Guidance for Medical Device Studies" (222 pages)
- "Regulations and Guidance on Clinical Investigator & IRB Responsibilities" (281 pages)
- "Administrative Simplification Provisions of HIPAA: The Act, Regulations, and DHHS (OCR) Guidance" (267 pages)
- "The EU Directive on GCP, Selected EU Guidances, and the Declaration of Helsinki" (181 pages)

Explanatory documents, such as FDA Information Sheets, are included to clarify and interpret the regulations and directives. The books are updated annually in April. While most of the material is available for free on government websites, finding it online can sometimes be frustrating, and identifying the most current version is problematic. In any case, the books are priced right at \$13.95 each; a few uses justify the purchase price.

Reverse-printed edge labels identify each section for easy access. The Drug Studies book includes an index to 21 CFR, which would be a welcome addition to the other volumes.

These books and others in the series are available at <http://www.clinicalresearchresources.com>.

Norman M. Goldfarb is Managing Partner of First Clinical Research, a provider of a clinical research best practices consulting, training, implementation and research services. Contact him at (650) 465-0119 or ngoldfarb@firstclinical.com.