

# JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

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"Can You Handle the Truth?"

## **"Good Clinical Practice in Canada" and "Good Clinical Practice in India"**

**Clinical Research Resources, 2005, 157 and 167 pages, \$13.95 each**

**Review by Norman M. Goldfarb**

Good news! Clinical Research Resources (CRR) has extended its series of 7" X 5-1/2" spiral-bound regulatory books to Canada and India. We can only hope that the series will continue to grow.

The Canada book includes:

- ICH Guideline (Step 5\*, Canada): Good Clinical Practice: Consolidated Guidance (ICH-E6)
- ICH Guideline (Step 5, Canada): Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (ICH-E2A)
- ICH Guideline (Step 5, Canada): Guidance on General Considerations for Clinical Trials (ICH-E8)
- Health Canada Division 5 Regulations and Extract from Regulatory Impact Statement
- Extract from Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, 1998 (with 2000, and 2002 updates)
- Declaration of Helsinki
- Belmont Report

\* Step 5 is the current ICH version.

The India book includes:

- Drug and Cosmetic Rules of 1945: Import of Manufacture of New Drug for Clinical Trials or Marketing (Rules 1,2,122-A,122-B, 122-D, 122-DA, 122, DAA, 122-DB, 122,DC, and122-E; Schedule Y)
- Guideline for Good Clinical Practices for Clinical Research in India

The books are updated annually in April. The material includes that most relevant to clinical research. 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, so just a few uses justify the purchase price.

Reverse-printed edge labels identify each section for easy access.

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

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