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"Can You Handle the Truth?"

"CRA Handbook, 2005 Edition"

Nancy J. Stark, Editor, 2005, 190 pages, Clinical Device Group, \$45.00

Review by Norman M. Goldfarb

Medical devices are the subject of a small but significant percentage of clinical trials. "CRA Handbook" addresses the neglected need of clinical research associates and site personnel for a compact compilation of the pertinent regulations and guidelines. The handbook includes both U.S. and E.U. material in a single volume.

Most of the handbook consists of regulations and guidelines:

- CFR Parts 812, 814, 11, 50, 54, 56, 99 and 820.30 (US)
- Medical Device Directive (EEC)
- Active Implantable Medical Device Directive (EEC)
- Guidelines for the Monitoring of Clinical Investigations (US)
- Expedited Review List (US)
- ISO 14155 Parts 1 and 2
- Declaration of Helsinki

The handbook also includes 15 pages of text, diagrams and flowcharts that explain important areas of the regulations. For example, four diagrams graphically present U.S. and E.U. reporting requirements for investigators and sponsors of different types of adverse events. U.S., but not E.U., regulations include the (undefined) concept of "unreasonable risk". If a serious AND unanticipated adverse event occurs that, in the sponsor's judgment, poses an unreasonable risk to study subjects, the sponsor must terminate the study within five days.

The book is available at <http://www.clinicaldevice.com/>.

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