

"Clinical Research Coordinator Handbook, Third Edition"

Deborrah Norris, 2004, 144 pages, Plexus Publishing, \$39.95

Review by Norman M. Goldfarb

"Clinical Research Coordinator Handbook, Third Edition" is an excellent resource for study coordinators, investigators and clinical research associates. This affordable and very clearly-written book includes three types of material:

- Brief explanations and comprehensive checklists cover a broad range of clinical research activities. This material provides a framework of key areas where expertise is required, without much elaboration.
- Detailed sections cover selected topics such as common CRF errors, clinical laboratory licenses, and FDA inspections. Some of this material is not included in books far more lengthy and costly than this one.
- Six appendices include forms, useful contacts, and a glossary.

This book has been selected for
[The First Clinical Research Bookshelf](#)
Essential reading for clinical research professionals

An extremely useful section details likely case-report-form errors and how to find them. There are four common types of "data offenders":

- Provide incomplete data
- Provide too much data (in the wrong place)
- Provide ambiguous data
- Misspell words

Thinking of setting up a clinical lab in your offices? There are five different types of CLIA (Clinical Lab Improvement Amendment of 1988) certificates for clinical laboratories. They are:

- Laboratory Certificate of Registration: Registration only; does not indicate compliance with federal CLIA requirements.
- Laboratory Certificate of Compliance: Indicates compliance with federal CLIA requirements based on inspection by the State Department of Health
- Laboratory Certificate of Accreditation: Indicates compliance with federal CLIA requirements based on inspection by a "Private Accrediting Agency"
- Laboratory Certificate of Provider-Performed Microscopy Procedures: Authorization for microscopy only
- Laboratory Certificate of Waiver: Authorization for "waived" tests that consumers can buy over the counter in a drug store.

There are also CAP (College of American Pathologists) certificates and, in the states of New York and Washington, state licenses that supersede the federal requirements.

Planning to host an FDA inspection? FDA investigators may interpret too much friendliness as an attempt to influence their findings, but not before learning things you may later regret sharing.

The book is available in bookstores.

Reviewer

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