

## Conducting Clinical Research: A Practical Guide for Physicians, Nurses, Study Coordinators, and Investigators

Stone J. 427 pages. Cumberland, MD: Mountainside MD Pr; 2006. \$69.95. ISBN 097491780X. Order at [www.conductingclinicalresearch.com](http://www.conductingclinicalresearch.com).

**Field of medicine:** Clinical research, especially for-profit pharmaceutical research.

**Format:** Softcover book.

**Audience:** Physicians, study nurses, study coordinators, and non-physician scientists.

**Purpose:** To “provide an overview of how research is conducted for drug companies and how (one) might become involved.”

**Content:** This guide, written from the point of view of a site principal investigator contracting with a for-profit pharmaceutical sponsor, successfully covers a broad range of topics related to the implementation of clinical trials of pharmaceutical products. Practical considerations for identifying sponsors and potential studies, evaluating contracts, initiating studies, completing enrollment, and passing an audit are all covered, along with insightful introductions to regulatory issues, patient safety, ethical considerations, and societal and political issues affecting clinical research. Many substantive insights garnered from the author’s own experience are included, and both the positive and negative aspects of conducting for-profit pharmaceutical research are fairly presented. Substantial background and resource information is included in 4 well-structured appendices.

**Highlights:** The text is well written and balances coverage of the relationships between for-profit entities and physician investigators with practical aspects of trial conduct. Information on contract negotiations and errors made by investigators is clearly presented. The author has an excellent sense of humor and appreciates the subtleties of the interactions between research participants and investigators.

**Limitations:** The author omitted some material that new investigators might find useful, such as examples of common errors in completing case report forms and resolving case report form queries. Information on classifying adverse events, such as explaining the confusing terms “serious” versus “severe” or determining severity and attribution, would also have been useful.

**Related readings:** While many texts have been written on the conduct of clinical trials, most are intended for statisticians or clinical scientists designing the trial (for example, Piantadosa’s *Clinical Trials: A Methodologic Perspective* [J Wiley, 2005] or Friedman and colleagues’ *Fundamentals of Clinical Trials* [Springer, 2006]) or for project managers implementing a multicenter trial (for example, Good’s *A Manager’s Guide to the Design and Conduct of Clinical Trials* [J Wiley, 2006]). Resources are lacking for the physician serving as a site investigator, and this work fills an important need.

**Reviewer:** Roger J. Lewis, MD, PhD, Harbor Medical Center, Torrance, California, and David Geffen School of Medicine and The Los Angeles Biomedical Research Institute, Los Angeles, California.

## Communicable Disease Control in Emergencies: A Field Manual

Connolly MA. 295 pages. Geneva: World Health Organization; 2006. \$36.00. ISBN 9241546166. Order at [www.who.int](http://www.who.int).

**Fields of medicine:** Public health, refugee medicine.

**Format:** Softcover book.

**Audience:** Clinical health professionals and public health coordinators working in refugee and disaster situations.

**Purpose:** To “promote effective, coordinated action towards the prevention and control of communicable diseases in emergencies.”

**Content:** This book contains a concise and thorough distillation of current recommendations for the control of communicable diseases in refugee and disaster settings. The book begins at the initial assessment with suggested survey team compositions, examples of survey techniques (including pros and cons of each), and the need for rapid dissemination of information to international coordinating and funding agencies. The discussion of disease prevention ranges from water delivery and placement of solid and human waste collection sites to burying the deceased. Important diseases are covered in a practical manner with applied examples.

**Highlights:** This well-structured and easy-to-navigate book covers the fundamental principles of rapid assessment, prevention, surveillance, outbreak control, and disease management. Each section of the book reminds the reader to consider the affected population’s customs and beliefs when developing programs and emphasizes coordination with local government and international agencies. Care is taken to ensure that dangerous situations are not created as a result of the interventions suggested and that such interventions are initiated at appropriate times. Every section concludes with suggested reading material, including a list of relevant World Health Organization (WHO) publications, videos, and Web sites. Annexes provide sample forms, treatment algorithms, and solid suggestions for collecting specimens and establishing clinical laboratories.

**Limitations:** The book is designed to be a field manual rather than a comprehensive textbook and is best used by trained professionals. The book contains treatment guidelines that are based on WHO recommendations, and most recommended readings are WHO publications. This keeps recommendations consistent but may present a limited point of view. The book has some typographical errors, most notably in the sexually transmitted infection flow charts.

**Related readings:** Lumley and colleagues’ *Handbook of the Medical Care of Catastrophes* (RSM Pr, 1996), Eddleston and colleagues’ *Oxford Handbook of Tropical Medicine* (Oxford Univ Pr, 2004), Heymann’s *Control of Communicable Diseases Manual* (American Public Health Assoc, 2004), and Ronald and Southall’s article “Refugee health: an approach to emergency situations” (BMJ. 1999; 318:200A) are helpful clinical additions.

**Reviewer:** Aric Gregson, MD, University of California, Los Angeles, Los Angeles, California.