Provides a practical "nuts and bolts" approach to the process of conducting clinical trials, identifying methods and techniques that can be replicated at other institutions and medical practices.

The Duke Clinical Research Institute (DCRI) is one of the world's leading academic clinical research organizations; its mission is to develop and share knowledge that improves the care of patients around the world through innovative clinical research.

Designed for investigators, research coordinators, CRO personnel, students, and others who have a desire to learn about clinical trials, this manual begins with an overview of the historical framework of clinical research, and leads the reader through a discussion of safety concerns and resulting regulations. Topics include Good Clinical Practice, informed consent, management of subject safety and data, as well as monitoring and reporting adverse events.

Updated to reflect recent regulatory and clinical developments, the manual reviews the conduct of clinical trials research in an increasingly global context. This new edition has been further expanded to include:

Ethical documents such as the Belmont Report and the Declaration of Helsinki are reviewed in relation to all aspects of clinical research, with a discussion of how researchers should apply the principles outlined in these important documents. This graphically appealing and eminently readable manual also provides sample forms and worksheets to facilitate data management and regulatory record retention; these can be modified and adapted for use at investigative sites.