INTRODUCTION

Clinical research is a complex undertaking that involves multiple stakeholders who provide checks and balances to the process of Good Clinical Practice (GCP) to support human subject protections and data integrity.

Sponsors generally plan, initiate and finance the trial and own the compounds or devices being developed. The sponsors commonly have multiple vendors helping to fulfill their responsibilities for a clinical trial. Vendors supplement sponsors resources and/or expertise—a contract research organization (CRO). The investigators and their study staff conduct investigations for sponsors. Study participants (also called subjects once they are consented and study procedures begin) can be healthy volunteers to critically ill incapacitated patients. There are also ethics committees (Institutional Review Boards) that are affiliated with an investigator(s) for a trial where the primary purpose is to ensure human subject protections related to a clinical trial being conducted at a research site. IRBs must approve the studies before an investigator can start enrolling subjects and must review and approve any changes. Last, but not least, the regulatory bodies (the FDA and the HHS in the U.S.) that regulate the research and make the final decision about whether or not the product is approved for marketing.

The focus of this text is specifically on the role of the study coordinator or clinical research coordinator (CRC) working in the clinical trials setting. Clinical trials are research studies that involve humans in the testing of potential new uses for an investigational product. This book was written particularly to help and educate CRCs, the people who work in conjunction with clinical investiga-tors at research sites. CRCs are the main liaison between the investigators and the study subjects, and between the site and the sponsor; they also handle a great deal of the study activity at clinical sites.

The book also looks at the many facets of clinical trials, from regulatory matters to the influences of technology. Concepts and relevant sections have been included in each chapter.

Whether the reader is a CRC or another stakeholder in clinical trials, or has an interest in learning more about the role, it is hoped you will find the book both informative and useful.

Karen was an outstanding researcher whose integral work will remain an endless reference for generations of CRCs to come. This process validates the importance of continuing education in clinical research and the importance of remaining aware and familiar with the changing regulations and industry practices. We must remain vigilant in our pursuit of information and critical knowledge, for ourselves and for future generations.

Thank you, Karen, for imparting your wisdom and experience, and for making everything so clear!