INTRODUCTION

My greatest motivation in completing the updates to the 2016 release of the *CRAs Guide to Monitoring Clinical Research* was to continue the tradition of excellence set by Karen Woodin's pivotal work; a training guide that has so strongly impacted the field of clinical research and my own clinical research career. The book is highly relevant and resonates in today's changing industry.

It felt surreal to review the book from a writer's perspective, when my last full review had been as a student preparing for an exam. I was starting the third year of my CRA career, and was preparing for the ACRP CCRA exam. There were countless prepatory manuals and courses from which to choose, and I was unclear on the best option for a field monitor. My supervisor simplified this convoluted process with a three word instruction—Read this book! And thus I was introduced to the *CRA's Guide* that gave the regulations sense, made rigid clinical content engaging, and made clear my understanding of what I believed was required—versus what was truly required—when monitoring. The *Guide* provided the information I needed to pass that critical test, and has served as a vital reference through all phases of my career.

I was honored to be part of the 2016 update process and strove to include the most relevant industry and regulatory information; technology and the evolving CRA role; the prevalence of web driven data collection and transmission; the broader scope of CRA responsibilities with site management; unblinded pharmacy monitoring; and risk based/remote monitoring practices. The industry has seen significant changes in the last five years: the transition of both small medical practices and large academic institutions to electronic medical records, electronic informed consent, and the smaller amount of 100% SDV and on-site monitoring practices. However the basic premise of the guide and contributing regulations that govern study conduct has not changed. They are the steady anchor in a sea of change.

Karen was an outstanding researcher whose integral work will remain an endless reference for generations of CRAs 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!