Compliance Today - September 2019
Shoulda-woulda-coulda

By Kelly M. Willenberg, DBA, RN, CCRP, CHRC, CHC

Kelly M. Willenberg (kelly@kellywillenberg.com) is President and CEO of Kelly Willenberg LLC in Greenville, SC.

My favorite part about the evolving world of research is the layer of efficiency that we have today. As a study coordinator 35 years ago, there was no automation at all. I kept a pocket-sized notebook with all of the studies I was responsible for. I kept a list of visit timelines for each of the protocols to refer to quickly. When we had an item that the sponsor was paying for in a trial, it was handled by a phone call. The person who received the call would go to the patient's account and manually take the charge off of the account. It was nowhere near a perfect way to do it. As a director of a large clinical trials office, my accounting system for invoicing sponsors was a "tickler" file or folder system. The paper was immense! I had monthly files, study files, and patient reminder files. I truly do not know how we kept up with it, but somehow, we did. My administrative officer would spend weekends with me so we could invoice sponsors each month. Why? We literally went into each patient's research binder to see where they were on the study. I have no qualms about how we did it back then, because we did what we needed to do in order to be compliant with good clinical practice and good business practice. But it was not an easy task!

Today various electronic systems make our lives more convenient, accrual faster, invoice processing more efficient, and also provide more human subjects protection for research participants. But in order to understand where we are headed, one must realize the ignorance out there on how the process really works. Research compliance professionals have to help add to the journey, not be an obstacle in it. I am recalcitrant too, so I definitely get it. The system use today safeguards from abuse, allows for more efficiency, resolves issues faster, provides training quickly, and overall makes clinical research professionals lives easier.

I love the technology available today. It is changing the way we do research and aids in compliance. Clinical trial management systems, e-regulatory systems, data banks, electronic medical records, accounting systems, just-in-time learning...the list goes on with what technologies are being implemented. Putting these systems in by placing blind trust that they will solve all of our compliance issues is not the option going forward. It's important that you get ahead of more panic that is yet to come, or the technology available will become another "shoulda-woulda-coulda" tool that may have enhanced your program!