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!