Research administration at academic medical centers should help clinical investigators navigate the complex research environment and operationalize research ideas. To effectively do this, the research culture must evolve from a model where individual faculty employ and trust only their own people to one of collaboration and trust of a much larger group of staff to help achieve scientific excellence. This means that staff and research support must deliver a high level of customer service and have a grounded conviction for what brings them to work every day.

The History
Five years ago, support for clinical research at Duke University School of Medicine was broken and narrowly scoped. Several years earlier, the School of Medicine clinical research support office was born out of a billing crisis and operational mandates that dictated to faculty, staff, schools, departments, centers, and institutes. The clinical research world prior to this was very “mom and pop,” as it is at many academic medical centers (AMCs). Our environment was fragmented with “do-it-yourself” (DIY) research work everywhere. Successful research staff did grow out of the DIY environment, but only for those who were lucky. I consider myself one of the “lucky” ones, but let’s break that down to see if others can relate.

Lucky
From 2000-2007, I managed several behavioral intervention studies funded by NIH for one investigator. This was a fortunate scenario for me in several ways: 1) I worked with an incredible, cross-disciplined team of experts so I learned daily; 2) We continued to be successful in NIH funding (R01s, R21s, etc); 3) I became known across campus as an expert in tumor registry data management and enrollment in these trials; 4) As the “expert” on the team in our study methods and implementation, I ran the projects soup to nuts and I loved it; 5) I’m an outgoing person so having relationships with people holding varying roles (faculty, other research coordinators, clinical experts, and senior staff in support offices, such as IRB) was easy. So, while all of this was lucky in setting myself up for a career at Duke, it is not reasonable for most staff. The principal investigator (PI) and I could not retain steady research assistance because there was limited opportunity for career development of those staff. While I wanted to grow the team of support for our research projects (and train the staff to know what I knew about operationalizing the studies), it was a lot of pressure for one investigator to be responsible for all of our funding. Thus, I continued to work long hours (alongside my PI, who wrote proposals and Duke received millions in funding). I kept asking myself, “why doesn’t our institution support the NIH investigator better? How is it that we have an office completely dedicated to clinical trials billing, but that barely acknowledges I exist? And we bring in all this funding?” I continued to express my ideas and the need for a new model. At this point, I was just a coordinator in the School of Nursing.
In 2007, an unexpected event occurred that spurred a dramatic change on our research team. A co-investigator passed away after a terminal diagnosis and the PI that I worked with decided to leave Duke. I’d built my career at Duke so I wasn’t ready to move my family and life across the country to continue being a project manager. Faculty approached me from across Duke to ask me to work for them. I waited. I still had this idea that research support for all faculty could be better.

Changing the Mindset
I started with relationships. I started helping all the faculty in the School of Nursing, and eventually agreed to take on an administrative position as a research practice manager (RPM). Serving as RPM allowed me new exposure to other areas of Duke. This is where I first became part of the larger clinical research oversight and support. My peers at the table were mostly very senior research coordinators who had run industry-sponsored clinical trials. We were from different worlds, but I could see commonalities. At this same time, a P20 grant at the School was ending and several research staff were losing their “soft-money funded” positions. I agreed to hire them to do the work on the numerous funded studies I was supporting. In turn, I would see if I could make a go of my idea to bring better research support to Duke. The nursing faculty trusted me because I helped them get their work done. Some started “purchasing” effort from members of my team for designated periods – thus began a shared effort model entitled, “Research Management Team (RMT)” (Snyder, 2012). This expanded to a service available to investigative teams across all of Duke. I sought and received funding for this from the Duke Clinical and Translational Science Award (CTSA) that led us to implement REDCap (Harris, 2009) for Duke.

In 2012, the vice dean for clinical research in the School of Medicine approached me to expand RMT’s service model even further for Duke and take on an existing research support office. While this opportunity was exciting to me, I knew it meant taking on a broken research support office. It was my only chance to continue moving my vision of research support forward. In July 2012, the Duke Office of Clinical Research (DOCR) was born: a rebranded, refreshed, yet-to-be-determined model of customer service support for the entire research community (Snyder, 2016). Building out the new office and DOCR model required acquiring additional senior staff who were in agreement that Duke could improve research support. In the next two years, I brought key leaders to our team that comprised expertise in information technology, nursing, Medicare coverage analysis, grant writing, industry-sponsored contract budgeting and reconciliation, legal, data management, study coordination, and staff management.

Moving the Vision Forward
For AMCs, research is a collaboration, not a service. There is a desire and drive to change patient care and health outcomes. When first taking on the office, this became our mission. First, change the culture of the central team, putting customer service first. Second, inspire staff by emphasizing that we’ve all chosen to work in AMCs because changing patient care and health outcomes is bigger than each of us. Together, the staff in clinical research must collaborate to be catalysts for change amongst the entire Duke research community. We must build partnerships based in trust with our faculty, patients, and local community. If staff only think about “me”, it will divert attention away from the true mission. To begin this journey for staff, we needed a complete overhaul of our job classifications. After

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several stakeholder discussions in 2014 that encompassed human resources, School of Medicine leadership, departments, centers, and institutes, we agreed to embark on a large-scale revision of job classifications for the Schools of Medicine and Nursing. Our timing could not have been better. The Core Competency Framework had just been published by the Joint Task Force for Clinical Trial Competency (Sonstein, 2014). We acknowledged that job responsibilities and roles had grown in need and scope, yet the job descriptions and classifications held by our staff had not—and this is true across AMCs (Stevens, 2015). Furthermore, training requirements and demands for professional development have climbed (Speicher, 2012). As of March 1, 2017, we have mapped nearly 700 staff into ten competency-based job classifications (Brouwer, 2017).

Clinical research matters. If we do not continue supporting our bright clinician-scientists to implement their best ideas, we will not continue to move remarkable, often life-saving, treatments and community health forward. Duke understands the need to retain the best and brightest staff. We cannot move the trust needle with the faculty if we don’t employ the most extraordinary, dedicated staff in clinical research. And this is only the beginning.

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