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Research compliance virtual sessions: Innovation from necessity

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If there were ever a time when we needed to discover an innovative way to be virtually present with research teams, it would be precisely in the midst of the COVID-19 outbreak. In research compliance, we needed inspiration to create, innovate, and tackle the limits of being distant, particularly when regulatory agencies issued guidance so that research studies could continue to operate safely. Like so many times before, we sought inspiration from one of Aesop's classical fables. This particular fable narrates the great intelligence of a crow who, fearing her demise, discovers a simple act that saved her life:

> A thirsty crow found a pitcher with some water in it, but so little was there that, try as she might, she could not reach it with her beak, and it seemed as though she would die of thirst within sight of the remedy. At last she hit upon a clever plan. She began dropping pebbles into the pitcher, and with each pebble the water rose a little higher until at last it reached the brim, and the knowing bird was enabled to quench her thirst.[1]

The Research Compliance Office at Children's Hospital Colorado (Children's Colorado) had to shift its focus: We knew we had to create a virtual way to connect consistently with research teams. Our compliance livelihood depended on the actions we would take. Yes, that is somewhat dramatic, we admit, but nevertheless, it conveys the seriousness of the formidable obstacles we encountered. More specifically, we knew that we would need to bridge regulatory and compliance gaps during worrisome and challenging times, that we would want to solve problems alongside teams, and that we would want to inspire innovative thinking in compliance practices. After all, necessity becomes the mother of invention.

Gathering virtually

In early March 2020, the global COVID-19 pandemic catapulted our Research Compliance Office into unorthodox working conditions. From one moment to the next, we plunged into working exclusively remotely. The spread of COVID-19 unquestionably burdened compliance initiatives and research activities and disrupted numerous aspects of compliance offices and research programs. Social distancing requirements and safety concerns, for example, immediately suspended our office's in-person research compliance rounding practice. Guided by the principle of closeness, our Research Compliance Office had placed immense value on being present where research activities happen. Much of our programmatic focus had centered on interacting meaningfully *in person* alongside research teams, not just in helping them identify vulnerabilities themselves, but also in dismantling misconstrued compliance practices. Because our program initiative of rounding had been upended, we

experienced uncertainty about how we could continue to be present in the spaces where research teams performed their research activities.

For all that the COVID-19 pandemic had managed to hinder, what it couldn't impede was our community's relentless desire to learn. Collaborative learning through quarterly workshops had been one area of focus in which the Research Compliance Office at Children's Colorado had experienced valuable success. Yet where 30 or more members of the research community once gathered for multiple sessions of these in-person workshops, safety protocols of working remotely discontinued any sort of in-person gatherings. When our compliance work turned exclusively remote, we knew we would have to pivot our focus in relation to education and collaboration. Then the anticipated happened: the deluge of regulatory guidance was issued by federal and state governments in order to help research programs make adjustments to address the extraordinary operational burdens and disruptions during the public health emergency.

March and April of 2020 saw several new and revised guidance documents[2] from regulatory agencies overseeing research, namely the U.S. Department of Health & Human Services Office for Human Research Protections,[3] the Office for Civil Rights (OCR),[4] National Institutes of Health,[5] and the Food and Drug Administration (FDA).[6] The regulatory guidance and flexibilities were intended to address the unforeseen disruptions to research operations. Even still, practical application in the local research context would still be required. For instance, although OCR's notification on Health Insurance Portability and Accountability Act enforcement discretion[7] explained some regulatory flexibilities in how protected health information (PHI) could be shared during the public health emergency, researchers remained perplexed with how to apply the flexibilities to research subject data. Additionally, the FDA offered considerations on conducting clinical trials,[8] including remote consent and telehealth considerations,[9] but how telehealth would be adopted in research remained uncertain.

Researchers and research team members alike, overwhelmed with the numerous and rapidly changing regulatory guidance and flexibilities, sought the best compliant practices from the Research Compliance Office. What became a necessity was to provide a consistent forum for collaborative learning while answering researchers' compliance questions. That necessity to innovate had unveiled itself: During a time when the situation was fraught with uncertainty, we, like the crow from the fable, "hit upon a clever plan." We designed and launched weekly Research Compliance Virtual Sessions, where we could engage with members of our research community, helping to ground and support one another while fostering collaborative learning during our COVID-19 circumstances.