

Report on Research Compliance Volume 18, Number 5. April 22, 2021 Shift to Trials as Standard of Care, Chaos to 'Normal': Research Admin Life Amid COVID

By Theresa Defino

In late February of last year, Kelly Cervellione was meeting with pulmonary medicine fellows when someone asked, “Did you hear about this COVID virus?” Another person said, “Oh, the clinical research department should look into remdesivir.” Cervellione, director of that department for Queens, New York-based MediSys Health Network, recalls responding, “OK, that’s some good information; let me look into it and see what’s going on.”

Within two weeks, the system, which includes Jamaica Hospital Medical Center and Flushing Hospital Medical Center, filed its first compassionate use application for remdesivir, with many more to follow. Jamaica Hospital later became one of the trial sites for the medication. Both hospitals now have research capacity and are “fully enrolling [patients] in COVID studies,” Cervellione said.

For Stephanie Scott, “alarm bells started ringing” about the same time, initially prompted by calls from investigators whose conferences had been cancelled. They wanted Scott, director of policy and research development in the Sponsored Projects Administration (SPA) at Columbia University and its Irving Medical Center, to tell them whether their nonrefundable travel costs could still be charged against a grant.

The next few months began what Scott referred to as a period of “chaos,” before settling into a “new normal” — of sorts. Cervellione, whose 700-bed facilities are in the throes of another wave of COVID-19 infections, is still waiting for some normalcy.

Cervellione and Scott shared their pandemic experiences as part of a conference^[1] organized by the Feinstein Institutes for Medical Research at Northwell Health, “Driving Responsible Conduct of Research During a Pandemic.” Their session in the conference, supported by the HHS Office of Research Integrity, focused on managing researchers’ “information overload” during the pandemic. The panel was moderated by James Mohler, Purdue University’s research integrity officer and associate dean of its graduate school.

While the scope and scale of their duties differ, Cervellione and Scott faced similar challenges. For example, both wrestled with getting information that they and researchers needed, which wasn’t always forthcoming and often was conflicting, particularly among funding agencies. Cervellione and Scott agreed it was better to share what they knew and to acknowledge what they didn’t.

“I think that I said, ‘I don’t know’ more in the past year than ever in my life. But I always followed it up with, ‘But I will look into it’ and [then] read and did some research and tried to provide the information that I could,” Cervellione said.

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