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Report on Research Compliance Volume 17, Number 5. April 23, 2020 Restarting Studies After COVID-19 Will Require Adaptations, Scrutiny of Study Site Capacities

By Theresa Defino

Alison Lakin, associate vice chancellor for regulatory compliance at the University of Colorado, Denver, Anschutz Medical Campus, acknowledged that it might seem inconceivable at the height of a pandemic to "start thinking about ramping back up research."

But she called this "the right time to be strategically thinking about how we efficiently, collaboratively and in a coordinated manner move forward" with clinical trials and ensure the safety of participants.

Heeding the call from governments and public health officials, much research on U.S. campuses has been shut down since the COVID-19 public health emergency was declared in March.[1] Universities and other institutions have scrambled to salvage what research they could, incorporating remote visits for clinical trial participants and, in some cases, allowing only studies related to COVID-19 to go ahead.

Lakin deemed the last two months "a challenging hiatus" and said more difficult times lie ahead, when clinical research is restarted. Nevertheless, "on a positive note…we have an opportunity…to collaborate together in a different way than we've done before. There are lessons that we can learn from this experience," she said.

Already Laskin has gained insights, including that research might be changed forever in some respects—with innovations like e-consents becoming common—and she also suspects that Americans are likely to have much greater interest in supporting drug development and may themselves be more eager to participate in research.

Restarting Studies After COVID-19

Despite all the preparation, "I don't think we'd ever planned for this one," said Lakin, "and I'm not sure that our normal prioritizing of reopening is actually going to work in this environment."

Lakin shared her views as part of a webinar series last month sponsored by the WIRB-Copernicus Group on the impact of COVID-19 on research.[2] She pointed out that one reason there may not be a return to "normal" is the expectation that the nation will suffer repeated outbreaks of the virus.

"We're going to be living in this era of potential waves of disease that are going to potentially impact us nationally, regionally, and [by] state," she said. "But the [research] sites are the real local level, and there may be the need to have…continued social distancing, whether it's continuous or intermittent. We're going to have to manage the unpredictability of potential hotspots coming up, even if things do move forward, away from the isolation."

The disruption of clinical sites is also likely to continue.

"As an academic institution, we work closely with large regional hospitals, and those hospitals are very much going to…continue to be focused on clinical care, more so than some other [research] sites," said Lakin. "We have to be thinking about ramping up in a more unstable world than we have been used to."

This means that sponsors need to be "very aware of your local context" and understand that different sites will return at different times, said Lakin. This will be unlike previous disasters when there might have been a "whole-scale change" that signaled when recovery was underway.