COSMOS
Navigate the Compliance Universe

Report on Research Compliance Volume 17, Number 5. April 23, 2020 With Continuing Review Optional, OSU Adopts Annual 'Check-In' Process, Increases Efficiencies

By Theresa Defino

For all its twists and turns, delays and revisions, the multiyear process of updating the Common Rule governing human subjects research was supposed to pay off for investigators and institutions in the form of fewer administrative burdens and red tape, and an embodiment of new study types and practices.

While much of that promise has yet to be realized, and some changes have actually increased tasks, at least one provision can ease study oversight without losing subject protections—namely the option to discontinue annual continuing review (CR) of certain research. And The Ohio State University (OSU) is one that has used this option to create efficiencies in its oversight process while assuring the research remains compliant with regulations and policies.

The process OSU put in place of CR, where appropriate, is called the Annual Status Report (ASR). The system has continued to be functional during the pandemic when most staffers are working from home, according to Andrew Hedrick, senior institutional review board (IRB) protocol analyst in OSU's Office of Responsible Research Practices.

Hedrick told *RRC* on April 15 that he was not aware of any problems with principal investigator (PI) access to the OSU system. "The only PI-facing aspect of our application process is web-based, so as long as the PI still has internet access, there should be no disruption. And they, of course, communicate via email, which has also not been disrupted," he said.

Regarding IRB staff, "other than working from home much longer than ever anticipated, not much really changed" with the CR/ASR process, said Hedrick.

"We all use laptops, and even before all this happened, we had the capability of accessing our work servers remotely via [virtual private network], and our online system can be accessed via web browser from anywhere," he told *RRC.* "Other than people having to move their monitors and docking equipment home temporarily, the overall process for CR and ASR has not been impacted all that much."

Variety of Studies Can Forgo CR

As published in 1991, the Common Rule[1] mandated that an IRB "shall conduct continuing review of research covered by [the regulation] at intervals appropriate to the degree of risk, but not less than once per year," a provision that didn't allow for exceptions.

As the Office for Human Research Protections (OHRP), which enforces the Common Rule for Public Health Service-funded research, explains, under the revised 45 C.F.R. § 46.110 , CR is not required for:

- "Research that is eligible for expedited review,
- "Exempt research conditioned on limited IRB review,

- "Research that has completed all interventions and now only includes analyzing data, even if the information or biospecimens are identifiable, [and]
- "Research that has completed all interventions and now only includes accessing follow-up clinical data from clinical care procedures."[2]

One caveat is that studies regulated by the Food and Drug Administration are not eligible to forgo CR because, to date, FDA has still not adopted the revised Common Rule.