

Report on Research Compliance Volume 15, Number 8. August 31, 2018 Three 'Burden-Reducing' Provisions in New Common Rule Proving to be Anything But

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Now that the compliance date is here for three “burden-reducing” provisions in the revised Common Rule and there’s still no final guidance from any federal agencies, institutions are reading the tea leaves to decide whether to voluntarily implement them early.

But given that triggering the three provisions may result in what an HHS advisor recently called “madness,” the consensus seems to be *why bother?* Institutions already must revise their relevant policies in preparation for the Jan. 21, 2019, general compliance date for changes to the human subject regulations.

HHS added drama to the seven-year saga by releasing three separate draft guidance documents on July 20, one day after the date when institutions were able to take advantage of these three provisions. The draft documents do not address some of the practical implications of implementing the three provisions that sparked consternation at a recent meeting of the HHS Secretary’s Advisory Committee on Human Research Protections (SACHRP).

In addition, on July 18, NIH posted a notice relieving all institutions of the current requirement to conduct review of applications, but reminding them to submit institutional review board (IRB) approval certifications through its just-in-time process, if funding is imminent. This could bring into question statements by the Office for Human Research Protections (OHRP) about the impact of implementing this and the other two provisions early.

On June 19, 2018, HHS and 16 other federal agencies—except, notably, the Food and Drug Administration—issued a final rule stating that July 19 would be the date that institutions were permitted to implement three provisions in the revised Common Rule it calls “burden-reducing” (RRC 7/18, p. 1). Perhaps optimistically, the rule estimates that 50% of “regulated entities will take advantage of the option included in this final rule to implement three burden-reducing provisions of the 2018 Requirements prior to the general compliance date.”

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