COSMOS
Navigate the Compliance Universe

Report on Research Compliance Volume 16, Number 2. February 28, 2019
After 8 Years, Many Delays and Still No Formal Guidance, Common Rule 'Fatigue' Takes Hold

By Theresa Defino

Weary and anxious might be two apt words to describe how some research compliance officials felt as the Jan. 21 date finally arrived for compliance with the long-awaited, oft-delayed Common Rule that governs federally supported human subjects research.

A sense of disassociation also prevailed because that date also was Martin Luther King Jr. Day—not to mention that much of the federal government had been shuttered for a month (see story, below).

"The upcoming compliance date that once felt so significant has been blunted in impact in part because it falls on a federal holiday and many of the Common Rule agencies other than HHS are currently shut down," Heather Pierce, senior director for science policy and regulatory counsel for the Association of American Medical Colleges (AAMC), told *RRC* a few days before Jan. 21.

Common Rule "fatigue" seems to be the most prevalent response as the deadline loomed, Pierce added, combined with a feeling that government-imposed delays didn't achieve their purpose.

"Most importantly, institutions are feeling as if they are going it on their own in interpretation and implementation," Pierce said. "The year-long delay in the compliance date was for the express purpose of giving the agencies additional time to develop, issue, and finalize guidance."

But, as of *RRC*'s deadline, the HHS Office for Human Research Protections (OHRP) had not issued a single final guidance document on the revisions, and its draft materials addressed somewhat odd topics and, at least in one case, may have arrived too late to matter.

Nearly eight years have passed since HHS, through OHRP, first issued an advance notice of proposed rulemaking (ANPRM) to revise and update the Common Rule. Since that time, research compliance officials, institutional review boards (IRBs), investigators and possibly research subjects have been caught in a vortex of changing requirements and whiplashed by a series of announced implementation dates that later were delayed, sometimes at the last minute.

Since the final rule was published in 2017, OHRP has had two years to develop and issue formal guidance (see related story below). However, as noted earlier, only draft documents have been issued to date. At some point, OHRP also posted a series of FAQs; the webpage where they are posted lists a July 20, 2018, date, but it does not appear that OHRP ever announced them (see http://bit.ly/2R0zFjJ).

On Jan. 18, without referencing these earlier FAQs, OHRP announced that it had posted a single FAQ. The unexpected FAQ posed the mouthful question: "How should IRBs approach the continuing review of research that remains active beyond long-term follow-up or data analysis, but that is eligible for expedited review under categories 8(b) or 9 of the 1998 OHRP Expedited Review List in light of the new provision at §46.109(f)(1)(i) of the 2018 requirements, which eliminates the requirement for such continuing review unless an IRB determines

otherwise?”