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As New Common Rule Compliance Date Ticks Closer, Hopes for Expected Delay Grow Dim

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Research compliance officials can be forgiven if they find themselves obsessively checking reginfo.gov, the federal website that shows the status of regulations being developed. Since fall, they've been waiting for word of a delay in the Jan. 19 compliance date for revised regulations governing human subjects research (*RRC 11/17, p. 11*).

A separate regulation that would effect a one-year delay for most of the revised provisions in 45 CFR Part 46, also known as the Common Rule, has been going through the clearance process run by the Office of Management and Budget (OMB) since Oct. 7, 2016. As of *RRC's* deadline, the rule was still branded on reginfo.gov with blue lettering: "under review."

Until that rule clears OMB and is published in the *Federal Register*, the extension remains in limbo and the compliance date for the Common Rule looms ever closer—yet another strange and troubling twist on the fraught, six-year saga to update the regulations for the first time since 1985.

"While it is still possible for a delay in the [Common] rule to come into effect before the compliance date, it is by no means guaranteed," Heather Pierce, regulatory counsel and senior director for science policy for the Association of American Medical Colleges (AAMC), told *RRC*. "Institutions should continue to consider how they will review research proposed after Jan. 19, 2018, if there is no change in the compliance date."

As published last year, the rule went into effect upon issuance but had a one-year compliance date for most provisions and a two-year date for mandatory use of a single institutional review board (sIRB) for multisite trials (*RRC 2/17, p. 1*).

But even that extra year is cold comfort, because NIH issued its own policy requiring the use of an sIRB in applicable research it funds, with a compliance date of Jan. 25 of this year. The date followed several delays. NIH still has not made clear when it will allow exceptions to this policy, although it did sketch out the process for granting them (*RRC 11/17, p. 1*).

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