

## Report on Research Compliance Volume 15, Number 2. February 28, 2018 Tumult Continues as Agencies Delay Revised Common Rule by a Minimum of Six Months

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Citing potential threats to the “safety” of human research subjects, HHS and 15 other federal agencies pulled a last-minute switcheroo and delayed both the effective and compliance dates of the 2017 revised Common Rule, making them both July 19.

The compliance date for the revised Common Rule regulations that govern human subjects research had been Jan. 19 for most provisions. Just two days before that date, the agencies issued an interim final rule imposing a six-month delay. But they also asked for feedback on whether a further delay was needed, allowing for a 60-day comment period. A proposed rule whose title indicates that three provisions could be delayed is still pending approval by the Office of Management and Budget (OMB).

Research compliance officials greeted the news with disbelief, rage and frustration—and maybe a little bit of relief. Many had spent months preparing to implement new policies and procedures required under the revised Common Rule, while hoping the compliance date might be changed but seeing nothing they could bank on (RRC 1/18, p. 1). Some were simply exasperated that a process begun in 2011 with an advance notice of proposed rulemaking still isn’t over.

The interim final rule announcing the delay was published online in the Public Inspection section of the *Federal Register* on Jan. 17 (RRC 1/18/18). It was published in the formal *Federal Register* on Jan. 22.

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