

Report on Research Compliance Volume 16, Number 2. February 28, 2019 Sudden Delays Marked Bumpy Path to Common Rule Rewrite

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On Jan. 21, organizations with federal funding for human subjects research were required to be in compliance with most of the provisions in a revised version of 45 C.F.R. part 46, also known as the Common Rule (see story, p. 1). The revisions include new requirements for consent forms and additional categories of studies considered exempt from federal rules (*RRC 2/17, p. 1*).

For federally supported but non-NIH funded research, the deadline for mandatory use of a single institutional review board for multisite research is Jan. 20, 2020. NIH imposed this requirement effective Jan. 25, 2018.

The process of developing and finalizing the regulation took nearly eight years. Despite the length of time, the federal government has yet to release any final guidance documents to aid compliance.

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