

Report on Research Compliance Volume 15, Number 5. May 31, 2018 Common Rule NPRM Sets 2019 Compliance Date, Muddles Prospects for Early Adoption

By Theresa Defino

In a surprise move, a new proposed rule prohibits institutions from getting a jump on complying with most provisions in the Common Rule governing human subjects research until January.

The notice of proposed rule-making (NPRM) published in the April 20 *Federal Register* left July 19 as the effective date but would “generally require regulated entities to continue to comply with the requirements of the current Common Rule (the ‘pre-2018 Requirements’) until January 21, 2019.”

A final rule, when published, may put to rest the issue of effective and compliance dates for revisions to the Common Rule, which have been in development since 2011 and subject to marked delays. More work follows, of course, as guidance must be developed, changes made and stakeholders acclimated. Publication of the NPRM prompted Misha Angrist, an associate professor at Duke University and a member of an institutional review board (IRB), to tweet the video of “The Song That Doesn’t End” from the Lamb Chop puppet television show.

The July 19 effective date has extremely limited applicability. It would allow institutions to implement a trio of specific provisions sooner than January, but the NPRM added a twist to this as well, making it an all-or-nothing proposition.

Generally the purpose of having different effective and compliance dates is to allow regulated entities time to begin implementing all provisions of a rule as soon as the effective date. Then compliance becomes mandatory at the time of the compliance date. In explicitly instructing organizations not to comply with the revisions until the January effective date, the Common Rule NPRM represents a break from the usual rule-making process.

Previously, the effective and compliance dates for the revised Common Rule had been the same—July 19 of this year (an extra year is allowed for a mandate to use a single institutional review board). The Council on Governmental Relations had sought 12 months between the July 19 effective date and any future compliance date for the new Common Rule.

A final rule is anticipated to be published quickly as July is approaching. It seems unlikely that a final rule would make many changes, given the whipsaw the research community has already endured.

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