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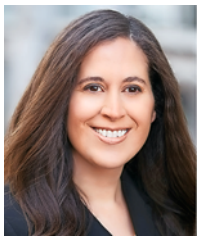
INSIGHT: Revised Common Rule Compliance Date Delayed Again



BY ANDREA FREY AND AMY JOSEPH

On June 18, 2018, the Department of Health and Human Services (HHS) and other federal departments and agencies issued a Final Rule announcing a six-month delay to the federal policy on the protection of human subjects, better known as the ''Common Rule.'' The Final Rule adopts proposals from a Notice of Proposed Rulemaking (''NPRM'') issued in April of this year, pursuant to which the general compliance date for the revised Common Rule will be delayed until Jan. 21, 2019.

Originally promulgated in 1991, the Common Rule was revised on Jan. 19, 2017 to address the changing landscape of research by enhancing protections for human subject participants and decreasing administrative and regulatory burdens for investigators, research institutions, and institutional review boards (''IRBs''), particularly for low-risk research. Referred to as the ''2018 Requirements,'' the updates to the rule were scheduled to take effect Jan. 19, 2018, until an interim final rule delayed general compliance to July 19, 2018. Subsequently, the NPRM proposed an additional 6-month delay to ''provide additional time to regulated entities for the preparations necessary to implement the 2018 Requirements.''

As a result of the Final Rule adopting the NPRM's proposals, regulated entities will generally be required to continue complying with the so-called ''pre-2018 requirements'' of the original Common Rule until Jan. 20, 2019. The one exception to this rule is that regulated entities are permitted (but not required) to implement, for certain studies, three burden-reducing provisions of the so-called ''2018 Requirements'' during the delay period. These three provisions include:

1. use of the revised definition of ''research,'' which deems four categories of activities not to be research;

2. elimination of the requirement for annual continuing review of certain categories of research; and

3. elimination of the requirement that IRBs review grant applications or other funding proposals related to the research.

The Final Rule clarifies that these three burden-reducing provisions may be implemented during the delay period only for those studies initiated prior to Jan. 21, 2019, that will eventually transition to compliance with the revised Common Rule (such election to transition the study must be documented). In other words, regulated entities now have three options for studies initiated prior to Jan. 21, 2019: (a) continue to comply with the pre-2018 requirements for the duration of the study, which are the default requirements if a regulated entity does not proactively elect compliance with the 2018 Requirements; (b) elect to transition the study on a date prior to Jan. 21, 2019, in which case the three burden-reducing provisions would apply during the interim period and compliance with the remainder of the 2018 Requirements would be required on Jan. 21, 2019; or (c) elect to transition a study to compliance with the 2018 Requirements as of a date on or after Jan. 21, 2019. Such decisions can be made on a case-by-case basis for each study. Research initiated on or after Jan. 21, 2019, must comply with all of the 2018 Requirements.

The delayed compliance date was anticipated given the significance of the revisions to the Common Rule and commentary provided from regulated entities ex-

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pressing frustration with the rollout of the revised rule and overall lack of guidance. In response, HHS stated in the Final Rule's commentary that adopting the NPRM's proposals offered ''the best balance of permitting institutions to implement several of the more straightforward provisions of the 2018 Requirements before the general compliance date, while granting Common Rule departments and agencies additional time to develop and issue key guidance documents, and granting institutions additional time to ensure that their operations are ready to implement the 2018 Requirements.'' HHS also provided that it ''will strive to issue guidance on key aspects of the 2018 Requirements as quickly as possible.''

Barring unforeseen circumstances, this is likely to be the final delay to the revised rule. In its commentary, HHS noted that it did not believe a delay of the general compliance date beyond Jan. 21, 2019 would be necessary for regulated entities to implement the 2018 requirements.

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