ROPES & GRAY ALERT

Health Care ▪ Life Sciences

June 19, 2018

Revisions to Common Rule Delayed Until January 21, 2019

In January 2017, the federal departments and agencies that follow the Federal Policy for the Protection of Human Subjects, typically referred to as the Common Rule, issued a Final Rule substantially revising and modernizing the Common Rule (summarized here). The revised Common Rule initially contained an effective and general compliance date of January 19, 2018, but as we reported in an earlier Alert, those dates were delayed until July 19, 2018 through an interim final rule published in January 2018. 83 Fed. Reg. 2,885 (Jan. 22, 2018). On April 20, 2018, the Common Rule departments and agencies issued a Notice of Proposed Rulemaking (the "April 2018 NPRM") that proposed to delay further by six months the general compliance date of the Common Rule revisions until January 21, 2019, while permitting institutions voluntarily to implement as of July 19, 2018 three "burden-reducing" provisions contained in the revised rule. 83 Fed. Reg. 17,595 (Apr. 20, 2018). On June 19, 2018, the Common Rule departments and agencies published a final rule adopting the proposals (the "June 2018 Final Rule"). 83 Fed. Reg. 28,497 (Jun. 19, 2018).

The June 2018 Final Rule delays the general compliance date of the Common Rule revisions until January 21, 2019, with the exception of the cooperative research provision (mandating single institutional review board ("IRB") oversight for certain research), for which the compliance date remains unchanged as January 20, 2020. Consistent with the proposed rule, the June 2018 Final Rule permits institutions voluntarily to implement three "burden-reducing" provisions of the revised Common Rule starting July 19, 2018. The three burden-reducing provisions, described in further detail in our April 2018 Alert, include:

1. Implementing the revised definition of "research" found at §__.102*(l)* of the revised Common Rule, which deems certain activities not to be research for purposes of the Common Rule.

2. Eliminating the requirement that IRBs review grant applications or proposals, found at §__.103(f) of the current Common Rule.

3. Allowing institutions not to conduct annual continuing review of certain categories of research, as specified at §__.109(f)(1)(i) and (iii) of the revised Common Rule.

Consistent with the April 2018 NPRM, the June 2018 Final Rule does not permit institutions to implement any other provisions of the revised Common Rule, such as the revised exemption categories, before the general compliance date of January 21, 2019.

The preamble of the June 2018 Final Rule provides additional commentary regarding implementation of the Common Rule revisions:

- First, the Common Rule departments and agencies state explicitly that "[w]e do not believe a delay of the general compliance date beyond January 21, 2019 is necessary," 83 Fed. Reg. 28,501, suggesting that further delay in implementation of the revised Common Rule is unlikely.

- Second, the Common Rule departments and agencies acknowledge the difficulty of implementing the Common Rule's revisions in the absence of guidance and state that they "will strive to issue guidance on key aspects of the [revised rule] as quickly as possible, while also engaging stakeholders." 83 Fed. Reg. 28,499. Thus, the Common Rule departments and agencies are expected to issue guidance implementing and

interpreting the revised Common Rule in the coming months and may allow the regulated community an opportunity to comment on such issuances.

- Third, the preamble makes clear that in implementing the three new "burden-reducing" provisions, institutions have flexibility to transition to the new provisions on a protocol-by-protocol basis, for an entire class of protocols, or for all protocols under review during the interim period. The preamble also notes that institutions have flexibility in how they document their transition to the new provisions, including documenting such a decision in IRB meeting minutes, through an IRB reviewer checklist, or in a spreadsheet created and maintained by the institution to keep track of which studies have been transitioned to the new provisions.

- Fourth, the preamble addresses a concern raised by comments to the proposed rule regarding the timing of the elimination of the "check-the-box" option in the federalwide assurance ("FWA"), by which institutions can voluntarily elect to subject all of their human subjects research to the Common Rule, even if the research is not federally funded. The elimination of the check-the-box option was announced as an administrative change separate from the Common Rule revisions in the January 2017 preamble to the final rule and thus is not required to be implemented at the same time as the revisions to the Common Rule's regulatory text. We discussed the implications of the elimination of the "check-the-box" option in states that maintain their own human subjects protection regulatory schemes, such as New York State, in a February 2017 Alert. The preamble to the June 2018 Final Rule states that additional information will be provided regarding the FWA process in advance of any modifications to the process. The preamble also clarifies that, with respect to FWAs issued by the Office for Human Research Protections ("OHRP"), any FWAs on file with OHRP will continue to be valid on and after January 21, 2019 for their effective period. The June 2018 Final Rule admonishes, however, that individual Common Rule departments and agencies have significant flexibility in what information is requested in the assurance process and states that questions about non-OHRP assurances will be addressed by the relevant Common Rule departments and agencies.

We will continue to monitor further developments regarding the revisions to the Common Rule as well as any accompanying guidance. Please contact your usual Ropes & Gray attorney if you wish to discuss these revisions in more detail.