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DECEMBER 18, 2018 | PUBLICATION

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Client Alert: U.S. Department of Health and Human Services ("HHS") Delays Effective and Compliance Date for the Revised Common Rule

Background

The Federal Policy for the Protection of Human Subjects, or the "Common Rule," was originally published in 1991 and has been adopted and codified in separate regulations by HHS and 15 other federal departments and agencies. On January 19, 2017, HHS and the other Common Rule departments and agencies published a revised Common Rule in the Federal Register ("Final Rule") which, according to the preamble, is intended to "modernize, strengthen and make more effective the Federal Policy for the Protection of Human Subjects that was originally promulgated as a Common Rule in 1991" and "better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators."

The long-awaited new requirements to the Common Rule were scheduled to become effective January 19, 2018 (with the exception of the revisions requiring a single institutional review board in cooperative research, for which the compliance date is January 20, 2020), and include significant changes which institutions, institutional review boards, researchers, and others involved in federally funded research involving human subjects should be aware of. Some of the major revisions include new definitions for "identifiable biospecimens" and "identifiable private information," new exemptions, and revised informed consent requirements.

On January 20, 2017, following the change of presidential administration, President Trump issued a memorandum to all executive departments and agencies imposing a regulatory freeze on any new or pending regulations issued at the close of the Obama administration, to allow Trump to review them. The Final Rule remained under administrative review for several months, causing uncertainty among members of the research community and requests for a delay of the compliance date, as set forth in a June 2017 letter from such members of the research community to HHS. In August 2017, the HHS Secretary's Advisory Committee on Human Research Protections also recommended that the implementation date for the Final Rule be delayed, due to uncertainty in the research community about whether the Final Rule would take effect on January 19, 2018, or whether the Final Rule would be delayed or modified by executive congressional action.

Subsequently, in October 2017, HHS proposed a rule titled "Federal Policy for the Protection of Human Subjects: Proposed 1-Year Delay of the General Implementation Date While Allowing the Use of Three Burden-Reducing Provisions During the Delay Year," which as of the date of this publication reflects that it is pending review by the Office of Information and Regulatory Affairs in the Office of Management and Budget. The proposed rule does not specify what the burden-reducing provisions are, however the proposed rule seems to correspond with the above-referenced June 2017 letter from members of the research community, in which the community asks HHS for permission to move forward with burden-reducing provisions, including certain exclusions and exemptions to the Common Rule requirements, elimination of the continuing review requirement for certain types of stages of research, and elimination of IRB review of grant applications.

Delay of Implementation

Fast forward to January 17, 2018, just two days before the Final Rule was scheduled to take effect, HHS and the other Common Rule departments and agencies announced and put on public display an interim final rule that would delay the Final Rule's effective and compliance date, pushing the date from January 19, 2018 to July 19, 2018 ("Interim Final Rule"). On January 22, 2018, the Interim Final Rule and commentary that discusses reasons for the delay of the effective date and compliance date of the Final Rule was published in the Federal Register. According to the Interim Final Rule, the reasons for delay include "the final rule's complexity, the absence of needed guidance, and the need to revamp institutional procedures and electronic systems in order to come into compliance with the requirements." The Interim Final Rule further states that HHS and the other Common Rule departments and agencies are in the process of developing a notice of proposed rulemaking to seek input from regulated entities and the public to further delay implementation of the Final Rule until January 21, 2019.

For the time being, unless HHS and the other Common Rule departments and agencies issue another delay, research initiated prior to July 19, 2018 will continue to be regulated by the current Common Rule, and regulated entities will be allowed to voluntarily comply with the Final Rule; while research initiated on or after July 19, 2018 will be required to comply with the Final Rule. We expect additional delays and guidance on how to implement the revisions to the Common Rule to be forthcoming.

Comments on the Interim Final Rule are due by March 19, 2018.

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