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HHS Delays Compliance Date for Revised Common Rule

On January 17, 2018, just two days before a final rule that revised the Common Rule was scheduled to take effect, the United States Department of Health and Human Services ("HHS") announced a six-month delay in the final rule's effective and compliance date. HHS has now issued an interim final rule whose effect is to postpone the compliance and effective dates of the revised Common Rule from January 19, 2018 to July 19, 2018. (Nevertheless, unchanged from the revised Common Rule, the requirement for single institutional review board ("IRB") review of multisite research will take effect on January 20, 2020.) On January 18, 2017, HHS together with fifteen other federal departments and agencies, had issued a final rule intended to revise and modernize the federal Policy for the Protection of Human Subjects (the Common Rule), the set of federal regulations governing clinical research involving human subjects. We previously described the key changes contained in the revisions to the Common Rule here, here, and here.

The interim final rule is intended to accomplish two objectives. First, it provides additional time to regulated entities to prepare for the implementation of the revised Common Rule. Second, the interim final rule grants HHS and other Common Rule federal departments and agencies the opportunity to seek additional public input and engagement on a further implementation delay. Specifically, HHS states in the preamble that it expects to issue a notice of proposed rulemaking "to fully engage regulated entities and the public regarding further delay of the 2018 Requirements until January 21, 2019." HHS will consider public comments on the interim final rule for 60 days.

The delay will be welcomed by many in the research community, as many stakeholders had been urging HHS to delay application of the 2017 final rule. As noted in the interim final rule, representatives of the regulated community, including the Association of American Medical Colleges, the Association of American Universities, and the Council of Governmental Relations, expressed concern about the ability of entities to implement the revised Common Rule by the initial compliance date of January 19, 2018. The HHS Secretary's Advisory Committee on Human Research Protections ("SACHRP") also recommended a delay in the compliance date. Notably, while certain stakeholders had asked that any delay in the effective date of the Common Rule revisions permit institutions to implement immediately certain burden-reducing provisions found in the Common Rule revisions, the interim final rule declined to take this approach and instead is requiring compliance with the pre-2018 rule until the new effective date of the final rule.

Unless HHS takes further regulatory action to delay the compliance date, research initiated on or after July 19, 2018 will be required to comply with the revised Common Rule. Studies that began earlier than that date must comply with the pre-2018 Common Rule requirements except that if the research continues on or after July 19, 2018, the institution will have flexibility to choose whether to comply with the pre-2018 Common Rule or the revised Common Rule.

Ropes & Gray will continue to monitor developments with respect to the Common Rule. If you have any questions, please contact any member of Ropes & Gray's health care or life sciences practice or your usual Ropes & Gray advisor.