

DELAY OF “2018 REQUIREMENTS” THAT REVISE THE COMMON RULE

The Federal Policy for the Protection of Human Subjects (the “Common Rule”) regulates the conduct of human subject research supported by federal agencies. On January 19, 2017, the Department of Health and Human Services (“HHS”), as well as 15 other federal agencies and departments that are subject to the Common Rule, published significant changes to the Common Rule in the Federal Register (“Final Rule”). This Final Rule, known as the “2018 Requirements,” was to take effect on January 19, 2018. Additional analysis regarding the 2018 Requirements can be found [here](#).

Instead, on January 17, 2018, an **Interim Final Rule** (“IFR”) delayed the effective date and the general compliance date of the Final Rule until July 19, 2018. The delay is intended to allow regulated entities more time to prepare to implement the 2018 Requirements. Additionally, HHS and the 15 other federal agencies and departments are in the process of seeking additional public comment through the notice and comment rulemaking process on a proposal regarding further delay of the 2018 Requirements until January 21, 2019.^[1]

EFFECT OF DELAY

A number of the proposed changes to the Common Rule were designed to make the regulations less burdensome for research that posed little or minimal risk to study participants. The delay means that regulated entities under the Common Rule are still required to comply with the **Common Rule Requirements of 2016** (“2016 Common Rule”). However, to the extent that the 2018 Requirements do not conflict with the 2016 Common Rule, regulated entities may incorporate such 2018 Requirements into their processes and procedures. Barring an additional delay in the 2018 Requirements, studies that begin before July 19, 2018 must comply with the 2016 Common Rule. This demarcation point ensures that studies must only comply with one set of rules, the rules in effect when the study began, and makes clear that any studies initiated prior to July 19, 2018 need not be updated to comply with the new 2018 Requirements midway through a study. In contrast, studies that begin after July 19, 2018 will be required to comply with the 2018 Requirements.

PRACTICAL TAKEAWAYS

In light of this delay, regulated entities should consider the following:

- Regulated entities may incorporate 2018 Requirements now **as long as those requirements do not conflict with the 2016 Common Rule**.
- Regulated entities should evaluate whether any of the 2018 Requirements have already been implemented and determine whether such implemented 2018 Requirements conflict with the 2016 Common Rule. In the event of a conflict between the 2018 Requirements and the 2016 Common Rule, ensure that the 2016 Common Rule is followed.

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[1] Note that the compliance date regarding revisions to the cooperative research provision included in the 2018 Requirements remains January 20, 2020.