

Delay of the Revised Common Rule: What Does It Mean Me?

What's the latest news?

July 19, 2018 is the new effective date and general compliance dat e for the revised Common Rule.

On January 17, 2018, an interim final rule (IFR), title <u>dederal Policy for the Protection of Human Subjects: Delay or</u> the Revisions to the Federal Policy for the Protection of Human Subjects as released. The IFR delays the effective date and general compliance date of the revised Common Rule ("the 2018 Requirements") for some since the cooperative research ("single IRB") provision, outlined at §__.114(b), whose compliance date remains January 20, 2020.

Why has this delay been announced

The six-month delay serves two purposes.

It allows institutions more time to prepare to implement the provisions of the revised Common Rule (now referred to as the 2018 Requirements)

It also allows federal departments and agencies time to review public comment on a possible notice of proposed rulemaking (NPRM) to delay the effective and compliance date even further. However, at this time institutions should proceed under the IFR and prepare for the July 19, 2018 effective and compliance date.

What does this mean for my institution's HRPP?

You have more time to prepare to implement the 2018 Requirements. The IFR cites the final rule's complete with the abser2021 of Requirements deprærate the energy interinterious addinformed consent required by §___116(b)(9), (c)(7)(9) in the 2018 Requirements do not conflict with the pre2018 rule, your institution could elect to incorporate these new elements in your consent forms before July 19. Your institution may NOT implement new provisions that conflict with the pre-