Focus on the Revised Common Rule

PRIM&R

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

What's the latest news?

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

On January 17, 2018, an interim final rule (IFR), titled Federal Policy for the Protection of Human Subjects: Delay of the Revisions to the Federal Policy for the Protection of Human Subjects, was released. The IFR delays the effective date and general compliance date of the revised Common Rule ("the 2018 Requirements") for six months. All provisions are covered except 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 complexity, the absence of needed guidance, and the need to revamp institutional policies, procedures, and systems in order to come into compliance, as primary reasons for the delay.
- **Between now and July 19, you will continue to review and approve studies under the current Common Rule ("the pre-2018 Requirements").** The pre-2018 Requirements are still in effect at this time.
- **Between now and July 19, you may elect to implement some 2018 Requirements, *as long as they do not conflict with the pre-2018 Requirements*.** For example, since the new elements of informed consent required by §__.116(b)(9), (c)(7)-(9) in the 2018 Requirements do not conflict with the pre-2018 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-2018 Requirements, such as ending continuing review for certain studies (as described in the 2018 Requirements at §__.109(f)). Because the pre-2018 regulations require continuing review at least annually for all ongoing non-exempt human subjects research, halting continuing review for such research before that date would be considered non-compliance.
- **Starting July 19, all NEW studies will be subject to the 2018 Requirements**. The IFR allows institutions to choose whether studies approved prior to July 19, 2018 (under the pre-2018 Requirements) remain under the pre-2018 Requirements, or be required to comply with the 2018 Requirements.

How can we use this additional time to prepare?

You now have until July 19, 2018, to continue to prepare to implement the new provisions of the revised Common Rule. Use the following strategies and resources to get started:

- **Educate yourself and your colleagues.** Visit primr.org/CommonRule to find workshops, conference sessions, and online resources with practical, thorough information for you and your HRPP, from leaders in the field.
- **Don't reinvent the wheel.** Review guides and tools developed by PRIM&R and others on our dedicated Resources & Tools page.
- **Share your resources.** If you've developed tools, charts, or SOPs in preparation for the new regulations, share them with PRIM&R. We'll post them on our website so others may benefit.
- **Raise your questions and concerns.** Post to the IRB Forum or the SBER Network to engage in discussion with colleagues in the field.