

January 31, 2018

# Interim Final Rule Delays Revised Common Rule Compliance Date (With Chance of More Delay)

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Researchers who have waited more than 25 years for updates to the Federal Policy for the Protection of Human Subjects (the “Common Rule”) will have to wait a little bit longer. On January 22, 2018, the U.S. Department of Health and Human Services (HHS) and several other federal agencies and departments (the “Agencies”) issued an [interim final rule](#) (“Interim Rule”) to delay the effective and general compliance dates of the Common Rule, as recently revised by the final rule issued by HHS on January 19, 2017 (“Revised Common Rule”),<sup>1</sup> from January 19, 2018 to July 19, 2018.<sup>2</sup>

Citing concerns from representatives of the regulated community, including HHS’ own advisory committee, the Agencies referenced regulatory complexity, a gap in necessary guidance, and the need to revamp institutional procedures and electronic systems as grounds to issue the delay without the opportunity for stakeholder input. The Agencies believe that the six-month delay will provide time for regulated entities to prepare for compliance with the Revised Common Rule, and for the Agencies both to create guidance documents on Revised Common Rule compliance and to seek input on whether to further delay implementation until January 21, 2019. The Interim Rule requires regulated entities to maintain the status quo until July 19, 2018. This means that:

- Studies involving human subjects that are initiated before July 19, 2018, must comply with the Common Rule as currently in effect until the Revised Common Rule goes into effect. After July 19, 2018, investigators performing research studies regulated under the Common Rule may opt to conform their studies to the Revised Common Rule upon approval and documentation by an institutional review board (IRB).
- Researchers are prohibited from complying with Revised Common Rule requirements that conflict with the existing Common Rule until

the Revised Common Rule becomes effective. This means that research organizations that revised their policies, procedures and technology infrastructure to comply with the Revised Common Rule on January 19, 2018, must revert to their prior infrastructure. To the extent that any of the Revised Common Rule requirements do not conflict with the existing Common Rule, regulated entities may – but are not required to – implement such non-conflicting provisions until the Revised Common Rule becomes effective.<sup>3</sup>

Some examples of Common Rule and Revised Common Rule requirements that do and do not conflict include:<sup>4</sup>

- **Conflicting Requirements:** The Revised Common Rule eliminates the existing Common Rule’s requirement for continuing IRB review at least annually for all ongoing non-exempt human subject research (as described in the Revised Common Rule at §\_\_.109(f)). Because the Revised Common Rule conflicts with existing Common Rule requirements, this provision may not be implemented before the Revised Common Rule becomes effective.
- **Non-Conflicting Requirements:** The Revised Common Rule addresses new elements to be included in an informed consent (Revised Common Rule at §\_\_.116(b)(9), (c)(7)-(9)). These new elements of consent may be added now because the existing Common Rule does not prohibit their inclusion.
- Unless further delayed, studies initiated on or after July 19, 2018, must comply with the Revised Common Rule.

1 82 Fed. Reg. 7149 (Jan. 19, 2017).

2 83 Fed. Reg. 2885 (Jan. 22, 2018).

3 83 Fed. Reg. at 2886; see also, Posting of Irene Stith-Coleman, irene.stith-coleman@hhs.gov, to OHRP-L@LIST.NIH.GOV (Jan. 17, 2018) (on file with authors).

4 Stith-Coleman, supra note 3.

The Interim Rule does not delay the compliance date for the cooperative research provision of the Revised Common Rule, which remains January 20, 2020.

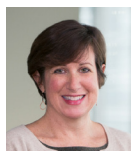
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If you have any questions about complying with the Common Rule when conducting research, please contact any member of Drinker Biddle's Health Care Team.

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