



DHHS published an NPRM delaying implementation of Revised Common Rule by an additional 6 months

Background

In a final rule published on January 19, 2017, federal departments and agencies made revisions to the Common Rule (the “2018 Requirements”). The 2018 Requirements were scheduled to become effective on January 19, 2018.

Federal departments and agencies later published an interim final rule delaying the effective and general compliance date for the 2018 Requirements until July 19, 2018.

NPRM published on April 20, 2018

The U.S. Department of Health and Human Services (HHS) and 16 other federal departments and agencies announced a *Notice of Proposed Rulemaking (NPRM)* proposing to delay for an additional 6 months the general compliance date for the revisions to the Federal Policy for the Protection of Human Subjects (the “Common Rule”).

This NPRM is intended to provide regulated entities additional time for the preparations necessary to implement the 2018 Requirements. If finalized, the NPRM would generally require regulated entities to continue to comply with the requirements of the current Common Rule (the “pre-2018 Requirements”) until January 21, 2019.

This NPRM requests comment on whether to permit institutions to implement the following provisions in the 2018 Requirements during the period that the general compliance date is delayed (July 19, 2018 until January 21, 2019). Those three provisions, intended to reduce burdens on regulated entities, are:

- (1) the revised definition of “research,” which deems four categories of activities not to be research;
- (2) the allowance for no annual continuing review of certain categories of research; and
- (3) the elimination of the requirement that institutional review boards (IRBs) review grant applications or other funding proposals related to the research.

Under the NPRM proposal:

- ◆ the compliance date would be changed from July 19, 2018, to January 21, 2019
- ◆ regulated entities would be required to comply with all pre-2018 Requirements during the period that the general compliance date is delayed
 - exception: if an institution chooses to substitute the three burden-reducing provisions of the 2018 Requirements for the comparable provisions of the pre-2018 Requirements

- institutions that choose to implement these three burden-reducing provisions for particular studies, such studies would be subject to the 2018 Requirements beginning on January 21, 2019

To access the NPRM Federal Register Notice, visit the following webpage:

<https://www.federalregister.gov/documents/2018/04/20/2018-08231/federal-policy-for-the-protection-of-human-subjects-proposed-six-month-delay-of-the-general>

To be assured consideration, comments on the NPRM must be received no later than 11:59 p.m. Eastern Standard Time on May 21, 2018. To submit comments during the open comment period or browse posted comments, visit the following webpage:

<https://www.regulations.gov/document?D=HHS-OPHS-2018-0007-0001>

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