

From: Irene Stith-Coleman <irene.stith-coleman@HHS.GOV>

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To: OHRP-L@LIST.NIH.GOV

Subject: **HHS and 16 Other Federal Departments and Agencies Issue a Final Rule to Delay for an Additional 6 Months the General Compliance Date of Revisions to the Common Rule While Allowing the Use of Three Burden-Reducing Provisions during the Delay Period**

Reply-To: Irene Stith-Coleman <irene.stith-coleman@HHS.GOV>

The U.S. Department of Health and Human Services (HHS) and 16 other federal departments and agencies are issuing a Final Rule to delay for an additional 6 months the general compliance date for changes recently made to the revised Federal Policy for the Protection of Human Subjects (also known as the Common Rule).

This policy was originally promulgated as a Common Rule in 1991, and was revised on January 19, 2017 (82 Fed. Reg. 7149) (the revised Common Rule is also known as the “2018 Requirements”). The effective and general compliance date for the 2018 Requirements was delayed to July 19, 2018 by an interim final rule that was published on January 22, 2018 (83 Fed. Reg. 2885). Subsequently, a Notice of Proposed Rulemaking (NPRM) was published on April 20, 2018 (83 FR 17595), which proposed an additional 6-month delay for the general compliance date for the 2018 Requirements and a flexibility that would allow regulated entities to take advantage of three burden-reducing provisions of the 2018 Requirements during the delay period.

The Final Rule adopts the proposals that were described in the April 2018 NPRM. The Final Rule delays the general compliance date of the 2018 Requirements for an additional 6-month period until January 21, 2019. The transition provision in the Final Rule is structured so that regulated entities cannot implement the revised Common Rule in its entirety, in lieu of compliance with the current version of the Common Rule, until the general compliance date of January 21, 2019. As a result of this delay to the general compliance date, regulated entities will be required, with an exception, to continue to comply with the requirements of the pre-2018 version of the Common Rule until January 21, 2019. The exception to this general rule is that institutions will be permitted (but not required) to implement, for certain studies, three burden-reducing provisions of the 2018 Requirements during the delay period (July 19, 2018 through January 20, 2019). The three provisions are:

- (1) The revised definition of “research,” which deems certain 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 review grant applications or other funding proposals related to the research.

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

The Final Rule has been put on public display by the Office of the Federal Register and can be accessed at: <https://www.federalregister.gov/documents/2018/06/19/2018-13187/protection-of-human-subjects-delay-of-general-compliance-date>.