The U.S. Department of Health and Human Services (HHS) and 16 other federal departments and agencies have issued 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 – 45CFR46) making the general compliance date of the 2018 Requirements now effective on January 21, 2019.

Background
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 making the general compliance date of the 2018 Requirements final and now effective on January 21, 2019.

The University of California, Berkeley, consistent with other campuses in the University of California System, has developed an implementation plan to accommodate the changes and provisions of the revised Common Rule that will go into effect on January 21, 2019. The Committee for Protection of Human Subjects (CPHS) and the Office for Human Subjects Protection (OPHS) will be disseminating these plans shortly. Investigators who conduct human subjects research should be attentive to email notices from OPHS and postings on the CPHS website regarding the upcoming changes.