

The Final Common Rule for Human Subjects Research Is Coming (Eventually)



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On January 19, 2017, the United States Department of Health and Human Services (“DHHS”) issued the Final Common Rule to revise Subpart A of the “Common Rule” governing human subjects research. (*Federal Policy for the Protection of Human Subjects*, 45 Code of Federal Regulations part 46). The Common Rule was promulgated in 1991 and adopted by several federal agencies as part of the effort to standardize research-related regulations for all institutions (and entities) that perform research involving the participation of human subjects. Beginning in 2011, DHHS, with the Executive Office of the President’s Office of Science and Technology Policy, sought to further simplify and modernize the regulations and oversight of research institutions. The Final Common Rule is the culmination of those efforts.

The Final Common Rule was scheduled to become effective on January 19, 2018. But earlier this week, DHHS along with several federal agencies announced an Interim Final Rule to delay the effective date and general compliance date for the Final Common Rule by six months. As a result, institutions may continue operating under the pre-2018 Common Rule until July 19, 2018. To the extent the revised provisions do not conflict with, or are not otherwise prohibited by, the pre-2018 Common Rule, institutions may begin complying with new Final Common Rule requirements in the interim. The Final Common Rule delayed the effective date for certain cooperative research requirements until January 2020, and this effective date has not changed.

According to the Office for Human Research Protections, the federal agencies issuing the Interim Final Rule are considering whether to further delay the required implementation date of the Final Common Rule beyond July 19, 2018.

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