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### Pondering Using the New Common Rule Early? SACHRP Has a Single Word of Advice: Don't

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The nation's highest-ranking advisory committee on human subjects research has some advice for institutions and investigators thinking of implementing provisions in the revised Common Rule before being required to do so on Jan. 21.

Save yourself the trouble and just don't.

Now, the situation might be different if the Secretary's Advisory Committee on Human Research Protections ruled the world, or, on a more realistic level, if the Office for Human Research Protections (OHRP) listens to SACHRP when issuing hoped-for guidance on early implementation and the related issue of transitioning studies begun before the effective date of the revised Common Rule.

Those are big ifs, and OHRP has a history of ignoring SACHRP's recommendations (*RRC 8/14, p. 1*). Nonetheless, at its recent two-day meeting, SACHRP ploughed through the primary "ambiguities that appear to have generated the most confusion amongst the research community" related to transitioning to the new rule, and offered its recommendations for how to resolve them.

To the overarching question of whether to transition at all, SACHRP is recommending that, because of uncertainty, "the most prudent course for researchers, IRBs [institutional review boards] and institutions is not to transition ongoing studies to the revised Common Rule until legally required to do so."

"It's our feeling that, because of these ambiguities...if the study has already been initiated under the old Common Rule, it is better to allow it to stay under the old Common Rule," said Mark Barnes, a former SACHRP member who currently serves as co-chair of its Subcommittee on Harmonization. "Otherwise, we will end up with so many permutations and combinations of studies and everything else that it will be increasingly difficult as we move through the transition date and, after the transition is made, for everyone to keep all their obligations straight and make sure they abide by them."

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