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Still a Muddle, OHRP Promises to Clarify sIRB Issues—But Not When

By Theresa Defino

Among the many challenges facing universities and others that conduct research that falls under the Common Rule^[1] is how to handle two related sets of requirements and deadlines—one imposed by the rule itself and the other by NIH. But information that might help clear up some questions will be forthcoming, Jerry Menikoff, director of the HHS Office for Human Research Protections (OHRP), recently promised. However, he couldn't say when that would be.

Menikoff made his pledge at a meeting of the Secretary's Advisory Committee on Human Research Protections (SACHRP) on Oct. 16.^[2] Also at the meeting, SACHRP approved recommendations that address pay-for-play studies.^[3]

Specifically, both NIH and the revised Common Rule mandated that “cooperative” research involving two or more U.S. sites utilize a single institutional review board (sIRB). NIH went first, issuing its final policy in June 2016 with a compliance date of May of the following year.^[4]

Implementation Marked by Delays

NIH's action came despite strong opposition from the research community, including from SACHRP, which argued that a mandate wasn't the best way to go and that encouraging voluntary adoption was enough.^[5]

Further complicating the situation was the fact that, when issued in draft form, the revised Common Rule had a similar requirement that wouldn't go into effect until much later than NIH's.^[6]

After a series of delay's, NIH's mandate went into effect Jan. 25, 2018.^[7]

Meanwhile, the final Common Rule published on Jan. 19, 2017—with just two days left in the Obama administration—established Jan. 19, 2018, as the general effective and compliance dates for all provisions except the sIRB requirement. That effective date for the sIRB mandate was set at Jan. 20, 2020—and it remains so today.^[8]

Compliance with the balance of the Common Rule provisions was also subject to changing deadlines. In June of 2018, a final rule established Jan. 21, 2019, for all but the sIRB provisions to be in effect for newly approved research.^[9]

As if this situation wasn't confusing enough, the two sIRB requirements aren't the same. NIH's, which is currently in effect, is narrower than the Common Rule's. Further, the situation is made more complex by still-lingering uncertainty surrounding some studies that fall, as SACHRP Chair Stephen Rosenfeld put it, into the “gap year” between compliance with all the general requirements and the sIRB mandate.

This latter issue was first raised publicly in May when the Council on Governmental Relations (COGR) and other

groups shared a letter they had written to Menikoff.^[10]

The groups noted that OHRP staff “have recently suggested in email correspondence...that cooperative research studies subject to the 2018 requirements (beginning on or after Jan. 21, 2019) are required to come into compliance beginning Jan. 20, 2020, such that studies that have already been approved by local IRBs and may be ongoing would need to be identified, paused, and undergo a new single IRB review.”

No previous statements by OHRP have indicated that “multisite studies initiated after the general compliance date” would have to “be transitioned to a single IRB review by the cooperative research provision compliance date,” the letter said. The groups requested that OHRP and the Common Rule agencies “expeditiously address this issue.”

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