Report on Research Compliance Volume 18, Number 6. May 20, 2021 SACHRP: Thorny Sponsor Interactions With Subjects Require Approval, Oversight

By Theresa Defino

Under the leadership of new chair Douglas Diekema, M.D., the Secretary's Advisory Committee on Human Research Protections (SACHRP) has forwarded its first recommendations of 2021 to new HHS Secretary Xavier Becerra. These address the need for institutional review boards (IRBs) and institutions to play a greater role in overseeing—and perhaps halting—certain activities by study sponsors that involve research subjects.[1]

Additionally, members weighed in on IRBs' authority to restrict data that result from research that in some way violates the HHS Common Rule or Food and Drug Administration (FDA) requirements (these recommendations will be addressed in a subsequent issue of *RRC*).[2]

The sponsor recommendations were drafted by SACHRP's Harmonization Subcommittee, led by Mark Barnes, partner with Ropes & Gray LLP, and David Forster, chief compliance officer for WIRB-Copernicus Group. SACHRP approved the recommendations at its March 23-24 meeting,[3] and they were recently posted to the website of the Office for Human Research Protections (OHRP).

The past several years have seen "an increasing relationship in both intensity and frequency between sponsors of research on the one hand and the research subjects and research subject families and disease advocacy groups on the other," Barnes explained at the meeting, "and this has led to a number of questions about…what is the appropriate role of a sponsor, either an industry sponsor or academic medical sponsor, in the course of interventional clinical research with living, breathing subjects."

The purposes of the recommendations are to "assess what the current problems are now that our researchers, IRBs and subjects and others have run into…and identify some of the issues that have arisen, but also to look at articulating some principles that we hope ultimately could find their way into guidance documents either at the FDA, at OHRP [or] at other agencies that fund and sponsor clinical research," he added.