

Report on Research Compliance Volume 19, Number 8. July 28, 2022 SACHRP Greets Long-Awaited Single IRB Draft Guidance With Gratitude; Seeks Much More Detail

By Theresa Defino

Research universities and other organizations have been employing single institutional review boards (sIRBs) for many years. NIH first announced an sIRB policy in June 2016, mandating their use for agency-funded multisite trials as of January 2018. In October 2016, the Secretary's Advisory Committee on Human Research Protections (SACHRP) developed "points to consider" regarding institutional review boards (IRBs), which it submitted to then-HHS Secretary Sylvia Burwell. [1]

In 2018, SACHRP again dove into the issue, at the request of the Office for Human Research Protections (OHRP), to which SACHRP indirectly reports, developing exceptions to the sIRB requirement. [2] Two years later, as of Jan. 20, 2020, under revisions to the Common Rule, U.S. agencies governmentwide required sIRBs for all federally supported domestic multisite trials (except those funded by the Department of Justice). [3]

Despite all this activity over the years, OHRP itself has been mostly silent on sIRBs. In a November 2019 document, the agency described the exceptions found in the regulations. But that changed with the surprise announcement in last month's *Federal Register* about the availability of OHRP's new draft guidance on the topic —issued in the form of FAQs. [5]

This document is only available to subscribers. Please log in or purchase access.

Purchase Login