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OHRP Belatedly Issues Two Categories of Single IRB Exceptions

HHS-funded research conducted at more than one U.S.-study site may continue to use multiple institutional review boards “if an IRB initially approved the research before Jan. 20, 2020,” the Office for Human Research Protections (OHRP) said Nov. 22. The announcement makes good on OHRP’s pledge to address requirements regarding single IRBs and which studies must comply (“Still a Muddle, OHRP Promises to Clarify sIRB Issues—But Not When,” RRC 16, no. 1).

The revised Common Rule governing federally supported human subjects research set a date of Jan. 20, 2020, for compliance with the single IRB requirement (other than NIH-funded studies, which had a deadline of Jan. 25, 2018, to comply). But questions arose as to whether multisite (also called cooperative) studies that began on or after the general compliance date of Jan. 21 “would need to be identified, paused, and undergo a new single IRB review,” as a group of research universities said in a letter to OHRP Director Jerry Menikoff in May. At that time, they asked OHRP to “expeditiously address this issue.” OHRP’s “determination” issued last month was an attempt to set the record straight. It noted that, in addition to the initiation date, other exceptions are when “the NIH single IRB policy does not apply, and the research was initially approved by an IRB before January 20, 2020, or NIH excepted the research from its single IRB policy” before Jan. 20, 2020.

[Link to single IRB determination announcement](#)

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