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◆ In light of the ongoing COVID-19 pandemic, the HHS Office for Human Research Protections has issued an exception to the single institutional review board policy—provided that the government sponsor agrees and “where reliance” on an sIRB would not be practical, OHRP announced Oct. 8. The exception applies to cooperative research “that is ongoing or initially reviewed by the IRB” during the pandemic and that would be in effect “for the duration of the research.”

“The COVID-19 public health emergency has created unprecedented burdens and disruption to the research enterprise, while at the same time requiring urgent research responses that necessitate flexible approaches to oversight in order to provide vital information and to allow other research to continue where possible,” OHRP said. “This exception represents an effort to prioritize the health and safety of both research subjects and investigators, and provides flexibility to institutions in seeking IRB review due to the unique challenges created by the COVID-19 outbreak.” OHRP also provided six examples where an sIRB might not be practical, which is part of the criteria for using the exception, applicable when “the HHS division supporting or conducting the research approves of the use of this exception.” The exception is effective for research that is “ongoing or initially reviewed by the IRB” during the COVID-19 public health emergency. First declared in January, HHS Secretary Alex Azar renewed the emergency on Oct. 2. Declarations are valid for 90 days. (10/15/20)

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