

# Report on Research Compliance Volume 17, Number 11. October 22, 2020 RRC E-Alerts: October 15, 2020

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## OHRP Grants Exemption to sIRB Mandate During Pandemic—With Caveats

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.

### OHRP exception announcement

#### Former Stony Brook Professor Sentenced to Prison for Grant Theft

Geoffrey Girnun was sentenced to a year and a day in prison, and he resigned his position as associate professor of pathology at Stony Brook University related to his theft of government funds stemming from his creation of two "sham" corporations that billed more than \$200,000 for purported materials for his cancer research. U.S. District Judge Denis Hurley also sentenced Girnun to forfeit \$225,000 and pay \$225,000 in restitution to NIH and Stoney Brook, which he had previously agreed to as part of a plea arrangement.

According to Department of Justice (DOJ), Girnun founded Atlas Metabolomics LLC and Empyrean Biosciences LLC in 2013 and 2017, respectively. "From approximately December 2013 to approximately September 2019, Girnun submitted fraudulent electronic invoices to Stony Brook University for payment to the sham companies for equipment, goods and services that were never received or provided," DOJ said on Oct. 6. Instead, Girnun used the funds "for personal expenses, including payments toward the mortgage on his residence and tuition for his children." Seth DuCharme, acting U.S. attorney for the Eastern District of New York, said Girnun's actions "undermined the important mission of his fellow researchers, who are dedicated to curing this deadly illness," and the mission of NIH and Stony Brook.

#### Link to announcement

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